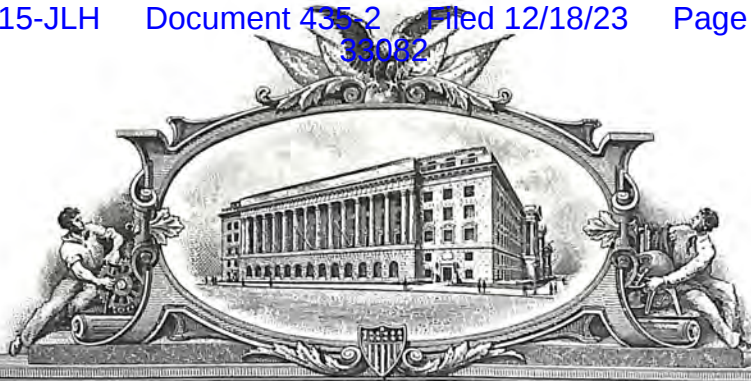


EXHIBIT 15

8234739

**THE UNITED STATES OF AMERICA****TO ALL TO WHOM THESE PRESENTS SHALL COME:****UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office**

April 25, 2022

**THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:**

APPLICATION NUMBER: 16/112,371**FILING DATE: August 24, 2018****PATENT NUMBER: 10,227,590****ISSUE DATE: March 12, 2019**

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



W. Montgomery
Wanda Montgomery
Certifying Officer

PTO/AIA/15 (10-17)

Approved for use through 11/30/2020. OMB 0551-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Attorney Docket No. 4140.01500B0	
		First Named Inventor Stephen Donald WILTON	
		Title See attached addendum	
		Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
--	---

1. <input type="checkbox"/> Fee Transmittal Form (PTO/SB/17 or equivalent) 2. <input checked="" type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27 3. <input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. <input checked="" type="checkbox"/> Specification [Total Pages <u>68</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <u>22</u>] 6. Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. <input type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> A copy from a prior application (37 CFR 1.63(d)) 7. <input checked="" type="checkbox"/> Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) <input type="checkbox"/> Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. <input checked="" type="checkbox"/> Computer Readable Form (CRF) b. <input type="checkbox"/> Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> Paper c. <input type="checkbox"/> Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. <input checked="" type="checkbox"/> 37 CFR 3.73(c) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee) 12. <input type="checkbox"/> English Translation Document (if applicable) 13. <input type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or PTO-1449) <input type="checkbox"/> Copies of citations attached 14. <input type="checkbox"/> Preliminary Amendment 15. <input type="checkbox"/> Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. <input type="checkbox"/> Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. <input type="checkbox"/> Other: <u>Authorization Under 37 C.F.R. 1.136(a)(3)</u> <u>Certification and Request for Prioritized Examination</u> <u>Under 37 CFR 1.102(e)</u>
--	---

*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS			
<input checked="" type="checkbox"/> The address associated with Customer Number: <u>153767</u> OR <input type="checkbox"/> Correspondence address below			
Name _____			
Address _____			
City _____	State _____	Zip Code _____	
Country _____	Telephone _____	Email _____	
Signature <u>/John M. Covert, #38,759/</u>		Date <u>Aug. 24, 2018</u>	
Name (Print/Type) <u>John M. Covert</u>		Registration No. (Attorney/Agent) <u>38,759</u>	

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

SRPT-VYDS-0005243

Addendum

ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING
AND METHODS OF USE THEREOF

Doc Code: TRACK1.REQ

Document Description: TrackOne Request

PTO/AIA/424 (04-14)

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	Stephen Donald WILTON	Nonprovisional Application Number (if known):	
Title of Invention:	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:
 - I. ☒ **Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**
 - i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
 - (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
 - ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.
 - II. ☐ **Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**
 - i. A request for continued examination has been filed with, or prior to, this form.
 - ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
 - iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
 - iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
 - v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature	/John M. Covert, #38,759/	Date	Aug. 24, 2018
Name (Print/Typed)	John M. Covert	Practitioner Registration Number	38,759
<p>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</p>			
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

SRPT-VYDS-0005245

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: WILTON *et al.*

Applicant: The University of Western
Australia

Application No.: *To Be Assigned*

Filed: August 24, 2018

Confirmation No.: *To Be Assigned*

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 4140.01500B0

Title: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND
METHODS OF USE THEREOF**

**Authorization to Treat a Reply as Incorporating an
Extension of Time Under 37 C.F.R. § 1.136(a)(3)**

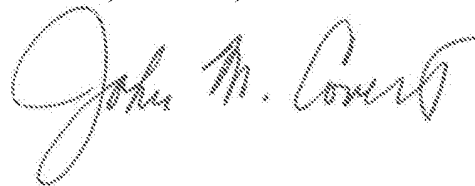
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert
Attorney for Applicant
Registration No. 38,759

Date: August 24, 2018

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
9891750_1.docx

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2:

<input type="checkbox"/>	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor 1 Remove				
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Stephen	Donald	WILTON	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Applecross	Country of Residence ⁱ	AU	
Mailing Address of Inventor:				
Address 1		18 Spey Road		
Address 2				
City	Applecross	State/Province		
Postal Code	6153	Country ⁱ	AU	
Inventor 2 Remove				
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Sue		FLETCHER	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Bayswater	Country of Residence ⁱ	AU	
Mailing Address of Inventor:				
Address 1		14 Roberts Street		
Address 2				
City	Bayswater	State/Province		
Postal Code	6053	Country ⁱ	AU	
Inventor 3 Remove				
Legal Name				

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

Prefix	Given Name	Middle Name	Family Name	Suffix
	Graham		MCCLOREY	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Bayswater	Country of Residence ⁱ	AU	

Mailing Address of Inventor:

Address 1	8 Digwood Close			
Address 2				
City	Bayswater	State/Province		
Postal Code	6053	Country ⁱ	AU	

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.**Add****Correspondence Information:**Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).☐ An Address is being provided for the correspondence Information of this application.

Customer Number	153767
Email Address	

Add Email**Remove Email****Application Information:**

Title of the Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
Attorney Docket Number	4140.01500B0	Small Entity Status Claimed	<input checked="" type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	22	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

Publication Information:

<input type="checkbox"/> Request Early Publication (Fee required at time of Request 37 CFR 1.219)
<input type="checkbox"/> Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

<p>Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative information during processing.</p>			
Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	153767		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
	Continuation of	15274772	2016-09-23		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15274772	Continuation of	14740097	2015-06-15	9605262	2017-03-28
Prior Application Status	Abandoned	Remove			
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14740097	Continuation of	13741150	2013-01-14		
Prior Application Status	Abandoned	Remove			
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
13741150	Continuation of	13168857	2011-06-24		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		4140.01500B0	
		Application Number			
Title of Invention		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF			

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13168857	Continuation of	12837359	2010-07-15	8232384	2012-07-31

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12837359	Continuation of	11570691	2008-01-15	7807816	2010-10-05

Prior Application Status		Expired		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11570691	a 371 of international	PCT/AU2005/000943	2005-06-28		

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)¹ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove			
Application Number	Country ¹	Filing Date (YYYY-MM-DD)	Access Code ¹ (if applicable)
2004903474	AU	2004-06-28	

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant 1			
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p>			
<div>Clear</div>			
<input checked="" type="radio"/> Assignee		<input type="radio"/> Legal Representative under 35 U.S.C. 117	
<input type="radio"/> Person to whom the inventor is obligated to assign.		<input type="radio"/> Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor: <input type="text"/>			
If the Applicant is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	The University of Western Australia		
Mailing Address Information For Applicant:			
Address 1	35 Stirling Highway		
Address 2			
City	Crawley	State/Province	
Country	AU	Postal Code	6009
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
If the Assignee or Non-Applicant Assignee is an Organization check here.			<input checked="" type="checkbox"/>
Organization Name	The University of Western Australia		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	35 Stirling Highway		
Address 2			
City	Crawley	State/Province	
Country ⁱ	AU	Postal Code	6009
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is **not** checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/John M. Covert, #38,759/		Date (YYYY-MM-DD)	2018-08-24	
First Name	John	Last Name	Covert	Registration Number	38759
Additional Signature may be generated within this form by selecting the Add button.					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	4140.01500B0
		Application Number	
Title of Invention	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		

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ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING
AND METHODS OF USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application is a continuation of U.S. Patent Application No. 15/274,772, filed September 23, 2016, now pending, which application is a continuation of U.S. Patent Application No. 14/740,097, filed June 15, 2015, now issued as U.S. Patent No. 9,605,262, which application is a continuation of U.S. Patent Application No. 13/741,150, filed January 14, 2013, now abandoned, which application is a continuation of U.S. Patent
10 Application No. 13/168,857, filed June 24, 2011, now abandoned, which application is a continuation of U.S. Patent Application No. 12/837,359, filed July 15, 2010, now issued as U.S. Patent No. 8,232,384, which application is a continuation of U.S. Patent Application No. 11/570,691, filed January 15, 2008, now issued as U.S. Patent No. 7,807,816, which application is a 35 U.S.C. § 371 National Phase Application of PCT/AU2005/000943, filed
15 June 28, 2005, which claims priority to Australian Patent Application No. 2004903474, filed June 28, 2004; which applications are each incorporated herein by reference in their entireties.

STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

20 This invention was made with government support under grant number R01 NS044146 awarded by the National Institutes of Health. The government has certain rights in the invention.

STATEMENT REGARDING SEQUENCE LISTING

25 The Sequence Listing associated with the application is provided in text format in lieu of a paper copy, and is hereby incorporated by reference into the specification. The name of the text file containing the Sequence Listing is 4140.01500B0_SL.txt. The text file is 62,078 bytes, was created on August 23, 2018 and is being submitted electronically via EFS-Web.

FIELD OF THE INVENTION

The present invention relates to novel antisense compounds and compositions suitable for facilitating exon skipping. It also provides methods for inducing exon skipping using the novel antisense compounds as well as therapeutic compositions
5 adapted for use in the methods of the invention.

BACKGROUND ART

Significant effort is currently being expended researching methods for suppressing or compensating for disease-causing mutations in genes. Antisense technologies are being developed using a range of chemistries to affect gene expression at a
10 variety of different levels (transcription, splicing, stability, translation). Much of that research has focused on the use of antisense compounds to correct or compensate for abnormal or disease-associated genes in a myriad of different conditions.

Antisense molecules are able to inhibit gene expression with exquisite specificity and because of this many research efforts concerning oligonucleotides as
15 modulators of gene expression have focused on inhibiting the expression of targeted genes such as oncogenes or viral genes. The antisense oligonucleotides are directed either against RNA (sense strand) or against DNA where they form triplex structures inhibiting transcription by RNA polymerase II. To achieve a desired effect in specific gene down-regulation, the oligonucleotides must either promote the decay of the targeted mRNA or
20 block translation of that mRNA, thereby effectively preventing *de novo* synthesis of the undesirable target protein.

Such techniques are not useful where the object is to up-regulate production of the native protein or compensate for mutations which induce premature termination of translation such as nonsense or frame-shifting mutations. Furthermore, in cases where a
25 normally functional protein is prematurely terminated because of mutations therein, a means for restoring some functional protein production through antisense technology has been shown to be possible through intervention during the splicing processes (Sierakowska H, *et al.*, (1996) Proc Natl Acad Sci USA 93, 12840-12844; Wilton SD, *et al.*, (1999)

Neuromusc Disorders 9, 330-338; van Deutekom JC *et al.*, (2001) Human Mol Genet 10, 1547-1554). In these cases, the defective gene transcript should not be subjected to targeted degradation so the antisense oligonucleotide chemistry should not promote target mRNA decay.

5 In a variety of genetic diseases, the effects of mutations on the eventual expression of a gene can be modulated through a process of targeted exon skipping during the splicing process. The splicing process is directed by complex multi-particle machinery that brings adjacent exon-intron junctions in pre-mRNA into close proximity and performs cleavage of phosphodiester bonds at the ends of the introns with their subsequent
10 reformation between exons that are to be spliced together. This complex and highly precise process is mediated by sequence motifs in the pre-mRNA that are relatively short semi-conserved RNA segments to which bind the various nuclear splicing factors that are then involved in the splicing reactions. By changing the way the splicing machinery reads or recognises the motifs involved in pre-mRNA processing, it is possible to create
15 differentially spliced mRNA molecules. It has now been recognised that the majority of human genes are alternatively spliced during normal gene expression, although the mechanisms invoked have not been identified. Using antisense oligonucleotides, it has been shown that errors and deficiencies in a coded mRNA could be bypassed or removed from the mature gene transcripts.

20 In nature, the extent of genetic deletion or exon skipping in the splicing process is not fully understood, although many instances have been documented to occur, generally at very low levels (Sherrat TG, *et al.*, (1993) Am J Hum Genet 53, 1007-1015). However, it is recognised that if exons associated with disease-causing mutations can be specifically deleted from some genes, a shortened protein product can sometimes be
25 produced that has similar biological properties of the native protein or has sufficient biological activity to ameliorate the disease caused by mutations associated with the target exon (Lu QL, *et al.*, (2003) Nature Medicine 9, 1009-1014; Aartsma-Rus A *et al.*, (2004) Am J Hum Genet 74: 83-92).

This process of targeted exon skipping is likely to be particularly useful in long genes where there are many exons and introns, where there is redundancy in the genetic constitution of the exons or where a protein is able to function without one or more particular exons (*e.g.* with the dystrophin gene, which consists of 79 exons; or possibly some collagen genes which encode for repeated blocks of sequence or the huge nebulin or titin genes which are comprised of ~80 and over 370 exons, respectively).

Efforts to redirect gene processing for the treatment of genetic diseases associated with truncations caused by mutations in various genes have focused on the use of antisense oligonucleotides that either: (1) fully or partially overlap with the elements involved in the splicing process; or (2) bind to the pre-mRNA at a position sufficiently close to the element to disrupt the binding and function of the splicing factors that would normally mediate a particular splicing reaction which occurs at that element (*e.g.*, binds to the pre-mRNA at a position within 3, 6, or 9 nucleotides of the element to be blocked).

For example, modulation of mutant dystrophin pre-mRNA splicing with antisense oligoribonucleotides has been reported both *in vitro* and *in vivo*. In one type of dystrophin mutation reported in Japan, a 52-base pair deletion mutation causes exon 19 to be removed with the flanking introns during the splicing process (Matsuo *et al.*, (1991) J Clin Invest., 87:2127-2131). An *in vitro* minigene splicing system has been used to show that a 31-mer 2'-O-methyl oligoribonucleotide complementary to the 5' half of the deleted sequence in dystrophin Kobe exon 19 inhibited splicing of wild-type *pre-mRNA* (Takeshima *et al.* (1995), J. Clin. Invest., 95, 515-520). The same oligonucleotide was used to induce exon skipping from the native dystrophin gene transcript in human cultured lymphoblastoid cells.

Dunckley *et al.*, (1997) Nucleosides & Nucleotides, 16, 1665-1668 described *in vitro* constructs for analysis of splicing around exon 23 of mutated dystrophin in the *mdx* mouse mutant, a model for muscular dystrophy. Plans to analyse these constructs *in vitro* using 2' modified oligonucleotides targeted to splice sites within and adjacent to mouse dystrophin exon 23 were discussed, though no target sites or sequences were given.

2'-O-methyl oligoribonucleotides were subsequently reported to correct dystrophin deficiency in myoblasts from the *mdx* mouse from this group. An antisense oligonucleotide targeted to the 3' splice site of murine dystrophin intron 22 was reported to cause skipping of the mutant exon as well as several flanking exons and created a novel in-frame dystrophin transcript with a novel internal deletion. This mutated dystrophin was expressed in 1-2% of antisense treated *mdx* myotubes. Use of other oligonucleotide modifications such as 2'-O-methoxyethyl phosphodiester are described (Dunckley *et al.* (1998) Human Mol. Genetics, 5, 1083-90).

Thus, antisense molecules may provide a tool in the treatment of genetic disorders such as Duchenne Muscular Dystrophy (DMD). However, attempts to induce exon skipping using antisense molecules have had mixed success. Studies on dystrophin exon 19, where successful skipping of that exon from the dystrophin pre-mRNA was achieved using a variety of antisense molecules directed at the flanking splice sites or motifs within the exon involved in exon definition as described by Errington *et al.* (2003) J Gen Med 5, 518-527".

In contrast to the apparent ease of exon 19 skipping, the first report of exon 23 skipping in the *mdx* mouse by Dunckley *et al.*, (1998) is now considered to be reporting only a naturally occurring revertant transcript or artefact rather than any true antisense activity. In addition to not consistently generating transcripts missing exon 23, Dunckley *et al.*, (1998) did not show any time course of induced exon skipping, or even titration of antisense oligonucleotides, to demonstrate dose dependent effects where the levels of exon skipping corresponded with increasing or decreasing amounts of antisense oligonucleotide. Furthermore, this work could not be replicated by other researchers.

The first example of specific and reproducible exon skipping in the *mdx* mouse model was reported by Wilton *et al.*, (1999) Neuromuscular Disorders 9, 330-338. By directing an antisense molecule to the donor splice site, consistent and efficient exon 23 skipping was induced in the dystrophin mRNA within 6 hours of treatment of the cultured cells. Wilton *et al.*, (1999), also describe targeting the acceptor region of the mouse dystrophin pre-mRNA with longer antisense oligonucleotides and being unable to repeat

the published results of Dunckley *et al.*, (1998). No exon skipping, either 23 alone or multiple removal of several flanking exons, could be reproducibly detected using a selection of antisense oligonucleotides directed at the acceptor splice site of intron 22.

While the first antisense oligonucleotide directed at the intron 23 donor splice site induced consistent exon skipping in primary cultured myoblasts, this compound was found to be much less efficient in immortalized cell cultures expressing higher levels of dystrophin. However, with refined targeting and antisense oligonucleotide design, the efficiency of specific exon removal was increased by almost an order of magnitude (see Mann CJ *et al.*, (2002) J Gen Med 4, 644-654).

Thus, there remains a need to provide antisense oligonucleotides capable of binding to and modifying the splicing of a target nucleotide sequence. Simply directing the antisense oligonucleotides to motifs presumed to be crucial for splicing is no guarantee of the efficacy of that compound in a therapeutic setting.

SUMMARY OF THE INVENTION

The present invention provides antisense molecule compounds and compositions suitable for binding to RNA motifs involved in the splicing of pre-mRNA that are able to induce specific and efficient exon skipping and a method for their use thereof.

The choice of target selection plays a crucial role in the efficiency of exon skipping and hence its subsequent application of a potential therapy. Simply designing antisense molecules to target regions of pre-mRNA presumed to be involved in splicing is no guarantee of inducing efficient and specific exon skipping. The most obvious or readily defined targets for splicing intervention are the donor and acceptor splice sites although there are less defined or conserved motifs including exonic splicing enhancers, silencing elements and branch points.

The acceptor and donor splice sites have consensus sequences of about 16 and 8 bases respectively (see Figure 1 for schematic representation of motifs and domains involved in exon recognition, intron removal and the splicing process).

According to a first aspect, the invention provides antisense molecules capable of binding to a selected target to induce exon skipping.

For example, to induce exon skipping in exons 3 to 8, 10 to 16, 19 to 40, 42 to 44, 46, 47, and 50 to 53 in the Dystrophin gene transcript the antisense molecules are
5 preferably selected from the group listed in Table 1A.

In a further example, it is possible to combine two or more antisense oligonucleotides of the present invention together to induce multiple exon skipping in exons 19-20, and 53. This is a similar concept to targeting of a single exon. A combination or "cocktail" of antisense oligonucleotides are directed at adjacent exons to
10 induce efficient exon skipping.

In another example, to induce exon skipping in exons 19-20, 31, 34 and 53 it is possible to improve exon skipping of a single exon by joining together two or more antisense oligonucleotide molecules. This concept is termed by the inventor as a "weasel", an example of a cunningly designed antisense oligonucleotide. A similar concept has been
15 described in Aartsma-Rus A *et al.*, (2004) Am J Hum Genet 74: 83-92).

According to a second aspect, the present invention provides antisense molecules selected and or adapted to aid in the prophylactic or therapeutic treatment of a genetic disorder comprising at least an antisense molecule in a form suitable for delivery to a patient.

20 According to a third aspect, the invention provides a method for treating a patient suffering from a genetic disease wherein there is a mutation in a gene encoding a particular protein and the affect of the mutation can be abrogated by exon skipping, comprising the steps of: (a) selecting an antisense molecule in accordance with the methods described herein; and (b) administering the molecule to a patient in need of such treatment.

25 The invention also addresses the use of purified and isolated antisense oligonucleotides of the invention, for the manufacture of a medicament for treatment of a genetic disease.

The invention further provides a method of treating a condition characterised by Duchenne muscular dystrophy, which method comprises administering to

a patient in need of treatment an effective amount of an appropriately designed antisense oligonucleotide of the invention, relevant to the particular genetic lesion in that patient. Further, the invention provides a method for prophylactically treating a patient to prevent or at least minimise Duchene muscular dystrophy, comprising the step of: administering to
5 the patient an effective amount of an antisense oligonucleotide or a pharmaceutical composition comprising one or more of these biological molecules.

The invention also provides kits for treating a genetic disease, which kits comprise at least a antisense oligonucleotide of the present invention, packaged in a suitable container and instructions for its use.

10 Other aspects and advantages of the invention will become apparent to those skilled in the art from a review of the ensuing description, which proceeds with reference to the following figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 Schematic representation of motifs and domains involved in exon
15 recognition, intron removal and the splicing process (SEQ ID NOS: 213 and 214).

Figure 2. Diagrammatic representation of the concept of antisense oligonucleotide induced exon skipping to by-pass disease-causing mutations (not drawn to scale). The hatched box represents an exon carrying a mutation that
20 prevents the translation of the rest of the mRNA into a protein. The solid black bar represents an antisense oligonucleotide that prevents inclusion of that exon in the mature mRNA.

Figure 3 Gel electrophoresis showing differing efficiencies of two antisense molecules directed at exon 8 acceptor splice site. The preferred compound
25 [H8A(-06+18)] induces strong and consistent exon skipping at a transfection concentration of 20 nanomolar in cultured normal human muscle cells. The less preferred antisense oligonucleotide [H8A(-06+14)] also induces efficient exon skipping, but at much higher concentrations. Other antisense

oligonucleotides directed at exon 8 either only induced lower levels of exon skipping or no detectable skipping at all (not shown).

Figure 4

Gel electrophoresis showing differing efficiencies of two antisense molecules directed at internal domains within exon 7, presumably exon splicing enhancers. The preferred compound [H7A(+45+67)] induces strong and consistent exon skipping at a transfection concentration of 20 nanomolar in cultured human muscle cells. The less preferred antisense oligonucleotide [H7A(+2+26)] induces only low levels of exon skipping at the higher transfection concentrations. Other antisense oligonucleotides directed at exon 7 either only induced lower levels of exon skipping or no detectable skipping at all (not shown).

Figure 5

Gel electrophoresis showing an example of low efficiency exon 6 skipping using two non-preferred antisense molecules directed at human exon 6 donor splice site. Levels of induced exon 6 skipping are either very low [H6D(+04-21)] or almost undetectable [H6D(+18-04)]. These are examples of non-preferred antisense oligonucleotides to demonstrate that antisense oligonucleotide design plays a crucial role in the efficacy of these compounds.

Figure 6

Gel electrophoresis showing strong and efficient human exon 6 skipping using an antisense molecules [H6A(+69+91)] directed at an exon 6 internal domain, presumably an exon splicing enhancer. This preferred compound induces consistent exon skipping at a transfection concentration of 20 nanomolar in cultured human muscle cells.

Figure 7

Gel electrophoresis showing strong human exon 4 skipping using an antisense molecule H4A(+13+32) directed at an exon 6 internal domain, presumably an exon splicing enhancer. This preferred compound induces strong and consistent exon skipping at a transfection concentration of 20 nanomolar in cultured human muscle cells,

- Figure 8A Gel electrophoresis showing strong human exon 12 skipping using antisense molecule H12A(+52+75) directed at exon 12 internal domain.
- Figure 8B Gel electrophoresis showing strong human exon 11 skipping using antisense molecule H11A(+75+97) directed at an exon 11 internal domain.
- 5 Figure 9A Gel electrophoresis showing strong human exon 15 skipping using antisense molecules H15A(+48+71) and H15A(-12+19) directed at an exon 15 internal domain.
- Figure 9B Gel electrophoresis showing strong human exon 16 skipping using antisense molecules H16A(-12+19) and H16A(-06+25).
- 10 Figure 10 Gel electrophoresis showing human exon 19/20 skipping using antisense molecules H20A(+44+71) and H20A(+149+170) directed at an exon 20 and a "cocktail" of antisense oligonucleotides H19A(+35+65, H20A(+44+71) and H20A(+149+170) directed at exons 19/20.
- Figure 11 Gel electrophoresis showing human exon 19/20 skipping using "weasels" directed at exons 19 and 20.
- 15 Figure 12 Gel electrophoresis showing exon 22 skipping using antisense molecules H22A(+125+106), H22A(+47+69), H22A(+80+101) and H22D(+13-11) directed at exon 22.
- Figure 13 Gel electrophoresis showing exon 31 skipping using antisense molecules H31D(+01-25) and H31D(+03-22); and a "cocktail" of antisense molecules directed at exon 31.
- 20 Figure 14 Gel electrophoresis showing exon 33 skipping using antisense molecules H33A(+30+56) and H33A(+64+88) directed at exon 33.
- Figure 15 Gel electrophoresis showing exon 35 skipping using antisense molecules H35A(+141+161), H35A(+116+135), and H35A(+24+43) and a "cocktail of two antisense molecules, directed at exon 35.
- 25 Figure 16 Gel electrophoresis showing exon 36 skipping using antisense molecules H32A(+49+73) and H36A(+26+50) directed at exon 36.

- Figure 17 Gel electrophoresis showing exon 37 skipping using antisense molecules H37A(+82+105) and H37A(+134+157) directed at exon 37.
- Figure 18 Gel electrophoresis showing exon 38 skipping using antisense molecule H38A(+88+112) directed at exon 38.
- 5 Figure 19 Gel electrophoresis showing exon 40 skipping using antisense molecule H40A(-05+17) directed at exon 40.
- Figure 20 Gel electrophoresis showing exon 42 skipping using antisense molecule H42A(-04+23) directed at exon 42.
- Figure 21 Gel electrophoresis showing exon 46 skipping using antisense molecule H46A(+86+115) directed at exon 46
- 10 Figure 22 Gel electrophoresis showing exon 51, exon 52 and exon 53 skipping using various antisense molecules directed at exons 51, 52 and 53, respectively. A "cocktail" of antisense molecules is also shown directed at exon 53.

BRIEF DESCRIPTION OF THE SEQUENCE LISTINGS

15

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
1	H8A(-06+18)	GAU AGG UGG UAU CAA CAU CUG UAA
2	H8A (-03+18)	GAU AGG UGG UAU CAA CAU CUG
3	H8A(-07+18)	GAU AGG UGG UAU CAA CAU CUG UAA G
4	H8A(-06+14)	GGU GGU AUC AAC AUC UGU AA
5	H8A(-10+10)	GUA UCA ACA UCU GUA AGC AC
6	H7A(+45+67)	UGC AUG UUC CAG UCG UUG UGU GG
7	H7A(+02+26)	CAC UAU UCC AGU CAA AUA GGU CUG G
8	H7D(+15-10)	AUU UAC CAA CCU UCA GGA UCG AGU A
9	H7A(-18+03)	GGC CUA AAA CAC AUA CAC AUA
10	C6A(-10+10)	CAU UUU UGA CCU ACA UGU GG
11	C6A(-14+06)	UUU GAC CUA CAU GUG GAA AG
12	C6A(-14+12)	UAC AUU UUU GAC CUA CAU GUG GAA AG
13	C6A(-13+09)	AUU UUU GAC CUA CAU GGG AAA G
14	CH6A(+69+91)	UAC GAG UUG AUU GUC GGA CCC AG
15	C6D(+12-13)	GUG GUC UCC UUA CCU AUG ACU GUG G
16	C6D(+06-11)	GGU CUC CUU ACC UAU GA
17	H6D(+04-21)	UGU CUC AGU AAU CUU CUU ACC UAU
18	H6D(+18-04)	UCU UAC CUA UGA CUA UGG AUG AGA

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
19	H4A(+13+32)	GCA UGA ACU CUU GUG GAU CC
20	H4D(+04-16)	CCA GGG UAC UAC UUA CAU UA
21	H4D(-24-44)	AUC GUG UGU CAC AGC AUC CAG
22	H4A(+11+40)	UGU UCA GGG CAU GAA CUC UUG UGG AUC CUU
23	H3A(+30+60)	UAG GAG GCG CCU CCC AUC CUG UAG GUC ACU G
24	H3A(+35+65)	AGG UCU AGG AGG CGC CUC CCA UCC UGU AGG U
25	H3A(+30+54)	GCG CCU CCC AUC CUG UAG GUC ACU G
26	H3D(+46-21)	CUU CGA GGA GGU CUA GGA GGC GCC UC
27	H3A(+30+50)	CUC CCA UCC UGU AGG UCA CUG
28	H3D(+19-03)	UAC CAG UUU UUG CCC UGU CAG G
29	H3A(-06+20)	UCA AUA UGC UGC UUC CCA AAC UGA AA
30	H3A(+37+61)	CUA GGA GGC GCC UCC CAU CCU GUA G
31	H5A(+20+50)	UUA UGA UUU CCA UCU ACG AUG UCA GUA CUU C
32	H5D(+25-05)	CUU ACC UGC CAG UGG AGG AUU AUA UUC CAA A
33	H5D(+10-15)	CAU CAG GAU UCU UAC CUG CCA GUG G
34	H5A(+10+34)	CGA UGU CAG UAC UUC CAA UAU UCA C
35	H5D(-04-21)	ACC AUU CAU CAG GAU UCU
36	H5D(+16-02)	ACC UGC CAG UGG AGG AUU
37	H5A(-07+20)	CCA AUA UUC ACU AAA UCA ACC UGU UAA
38	H5D(+18-12)	CAG GAU UGU UAC CUG CCA GUG GAG GAU UAU
39	H5A(+05+35)	ACG AUG UCA GUA CUU CCA AUA UUC ACU AAA U
40	H5A(+15+45)	AUU UCC AUC UAC GAU GUC AGU ACU UCC AAU A
41	H10A(-05+16)	CAG GAG CUU CCA AAU GCU GCA
42	H10A(-05+24)	CUU GUC UUC AGG AGC UUC CAA AUG CUG CA
43	H10A(+98+119)	UCC UCA GCA GAA AGA AGC CAC G
44	H10A(+130+149)	UUA GAA AUC UCU CCU UGU GC
45	H10A(-33-14)	UAA AUU GGG UGU UAC ACA AU
46	H11D(+26+49)	CCC UGA GGC AUU CCC AUC UUG AAU
47	H11D(+11-09)	AGG ACU UAC UUG CUU UGU UU
48	H11A(+118+140)	CUU GAA UUU AGG AGA UUC AUC UG
49	H11A(+75+97)	CAU CUU CUG AUA AUU UUC CUG UU
50	H12A(+52+75)	UCU UCU GUU UUU GUU AGC CAG UCA
51	H12A(-10+10)	UCU AUG UAA ACU GAA AAU UU

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
52	H12A(+11+30)	UUC UGG AGA UCC AUU AAA AC
53	H13A(+77+100)	CAG CAG UUG CGU GAU CUC CAC UAG
54	H13A(+55+75)	UUC AUC AAC UAC CAC CAC CAU
55	H13D(+06-19)	CUA AGC AAA AUA AUC UGA CCU UAA G
56	H14A(+37+64)	CUU GUA AAA GAA CCC AGC GGU CUU CUG U
57	H14A(+14+35)	CAU CUA CAG AUG UUU GCC CAU C
58	H14A(+51+73)	GAA GGA UGU CUU GUA AAA GAA CC
59	H14D(-02+18)	ACC UGU UCU UCA GUA AGA CG
60	H14D(+14-10)	CAU GAC ACA CCU GUU CUU CAG UAA
61	H14A(+61+80)	CAU UUG AGA AGG AUG UCU UG
62	H14A(-12+12)	AUC UCC CAA UAC CUG GAG AAG AGA
63	H15A(-12+19)	GCC AUG CAC UAA AAA GGC ACU GCA AGA CAU U
64	H15A(+48+71)	UCU UUA AAG CCA GUU GUG UGA AUC
65	H15A(+08+28)	UUU CUG AAA GCC AUG CAC UAA
66	H15D(+17-08)	GUA CAU ACG GCC AGU UUU UGA AGA C
67	H16A(-12+19)	CUA GAU CCG CUU UUA AAA CCU GUU AAA ACA A
68	H16A(-06+25)	UCU UUU CUA GAU CCG CUU UUA AAA CCU GUU A
69	H16A(-06+19)	CUA GAU CCG CUU UUA AAA CCU GUU A
70	H16A(+87+109)	CCG UCU UCU GGG UCA CUG ACU UA
71	H16A(-07+19)	CUA GAU CCG CUU UUA AAA CCU GUU AA
72	H16A(-07+13)	CCG CUU UUA AAA CCU GUU AA
73	H16A(+12+37)	UGG AUU GCU UUU UCU UUU CUA GAU CC
74	H16A(+92+116)	CAU GCU UCC GUC UUC UGG GUC ACU G
75	H16A(+45+67)	G AUC UUG UUU GAG UGA AUA CAG U
76	H16A(+105+126)	GUU AUC CAG CCA UGC UUC CGU C
77	H16D(+05-20)	UGA UAA UUG GUA UCA CUA ACC UGU G
78	H16D(+12-11)	GUA UCA CUA ACC UGU GCU GUA C
79	H19A(+35+53)	CUG CUG GCA UCU UGC AGU U
80	H19A(+35+65)	GCC UGA GCU GAU CUG CUG GCA UCU UGC AGU U
81	H20A(+44+71)	CUG GCA GAA UUC GAU CCA CCG GCU GUU C
82	H20A(+147+168)	CAG CAG UAG UUG UCA UCU GCU C
83	H20A(+185+203)	UGA UGG GGU GGU GGG UUG G
84	H20A(-08+17)	AUC UGC AUU AAC ACC CUC UAG AAA G
85	H20A(+30+53)	CCG GCU GUU CAG UUG UUC UGA GGC
86	H20A(-11+17)	AUC UGC AUU AAC ACC CUC UAG AAA GAA A
87	H20D(+08-20)	GAA GGA GAA GAG AUU CUU ACC UUA CAA A
88	H20A(+44+63)	AUU CGA UCC ACC GGC UGU UC

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
89	H20A(+149+168)	CAG CAG UAG UUG UCA UCU GC
90	H21A(-06+16)	GCC GGU UGA CUU CAU CCU GUG C
91	H21A(+85+106)	CUG CAU CCA GGA ACA UGG GUC C
92	H21A(+85+108)	GUC UGC AUC CAG GAA CAU GGG UC
93	H21A(+08+31)	GUU GAA GAU CUG AUA GCC GGU UGA
94	H21D(+18-07)	UAC UUA CUG UCU GUA GCU CUU UCU
95	H22A(+22+45)	CAC UCA UGG UCU CCU GAU AGC GCA
96	H22A(+125+106)	CUG CAA UUC CCC GAG UCU CUG C
97	H22A(+47+69)	ACU GCU GGA CCC AUG UCC UGA UG
98	H22A(+80+101)	CUA AGU UGA GGU AUG GAG AGU
99	H22D(+13-11)	UAU UCA CAG ACC UGC AAU UCC CC
100	H23A(+34+59)	ACA GUG GUG CUG AGA UAG UAU AGG CC
101	H23A(+18+39)	UAG GCC ACU UUG UUG CUC UUG C
102	H23A(+72+90)	UUC AGA GGG CGC UUU CUU C
103	H24A(+48+70)	GGG CAG GCC AUU CCU CCU UCA GA
104	H24A(-02+22)	UCU UCA GGG UUU GUA UGU GAU UCU
105	H25A(+9+36)	CUG GGC UGA AUU GUC UGA AUA UCA CUG
106	H25A(+131+156)	CUG UUG GCA CAU GUG AUC CCA CUG AG
107	H25D(+16-08)	GUC UAU ACC UGU UGG CAC AUG UGA
108	H26A(+132+156)	UGC UUU CUG UAA UUC AUC UGG AGU U
109	H26A(-07+19)	CCU CCU UUC UGG CAU AGA CCU UCC AC
110	H26A(+68+92)	UGU GUC AUC CAU UCG UGC AUC UCU G
111	H27A(+82+106)	UUA AGG CCU CUU GUG CUA CAG GUG G
112	H27A(-4+19)	GGG GCU CUU CUU UAG CUC UCU GA
113	H27D(+19-03)	GAC UUC CAA AGU CUU GCA UUU C
114	H28A(-05+19)	GCC AAC AUG CCC AAA CUU CCU AAG
115	H28A(+99+124)	CAG AGA UUU CCU CAG CUC CGC CAG GA
116	H28D(+16-05)	CUU ACA UCU AGC ACC UCA GAG
117	H29A(+57+81)	UCC GCC AUC UGU UAG GGU CUG UGC C
118	H29A(+18+42)	AUU UGG GUU AUC CUC UGA AUG UCG C
119	H29D(+17-05)	CAU ACC UCU UCA UGU AGU UCC C
120	H30A(+122+147)	CAU UUG AGC UGC GUC CAC CUU GUC UG
121	H30A(+25+50)	UCC UGG GCA GAC UGG AUG CUC UGU UC
122	H30D(+19-04)	UUG CCU GGG CUU CCU GAG GCA UU
123	H31D(+06-18)	UUC UGA AAU AAC AUA UAC CUG UGC
124	H31D(+03-22)	UAG UUU CUG AAA UAA CAU AUA CCU G
125	H31A(+05+25)	GAC UUG UCA AAU CAG AUU GGA
126	H31D(+04-20)	GUU UCU GAA AUA ACA UAU ACC UGU
127	H32D(+04-16)	CAC CAG AAA UAC AUA CCA CA
128	H32A(+151+170)	CAA UGA UUU AGC UGU GAC UG
129	H32A(+10+32)	CGA AAC UUC AUG GAG ACA UCU UG

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
130	H32A(+49+73)	CUU GUA GAC GCU GCU CAA AAU UGG C
131	H33D(+09-11)	CAU GCA CAC ACC UUU GCU CC
132	H33A(+53+76)	UCU GUA CAA UCU GAC GUC CAG UCU
133	H33A(+30+56)	GUC UUU AUC ACC AUU UCC ACU UCA GAC
134	H33A(+64+88)	CCG UCU GCU UUU UCU GUA CAA UCU G
135	H34A(+83+104)	UCC AUA UCU GUA GCU GCC AGC C
136	H34A(+143+165)	CCA GGC AAC UUC AGA AUC CAA AU
137	H34A(-20+10)	UUU CUG UUA CCU GAA AAG AAU UAU AAU GAA
138	H34A(+46+70)	CAU UCA UUU CCU UUC GCA UCU UAC G
139	H34A(+95+120)	UGA UCU CUU UGU CAA UUC CAU AUC UG
140	H34D(+10-20)	UUC AGU GAU AUA GGU UUU ACC UUU CCC CAG
141	H34A(+72+96)	CUG UAG CUG CCA GCC AUU CUG UCA AG
142	H35A(+141+161)	UCU UCU GCU CGG GAG GUG ACA
143	H35A(+116+135)	CCA GUU ACU AUU CAG AAG AC
144	H35A(+24+43)	UCU UCA GGU GCA CCU UCU GU
145	H36A(+26+50)	UGU GAU GUG GUC CAC AUU CUG GUC A
146	H36A(-02+18)	CCA UGU GUU UCU GGU AUU CC
147	H37A(+26+50)	CGU GUA GAG UCC ACC UUU GGG CGU A
148	H37A(+82+105)	UAC UAA UUU CCU GCA GUG GUC ACC
149	H37A(+134+157)	UUC UGU GUG AAA UGG CUG CAA AUC
150	H38A(-01+19)	CCU UCA AAG GAA UGG AGG CC
151	H38A(+59+83)	UGC UGA AUU UCA GCC UCC AGU GGU U
152	H38A(+88+112)	UGA AGU CUU CCU CUU UCA GAU UCA C
153	H39A(+62+85)	CUG GCU UUC UCU CAU CUG UGA UUC
154	H39A(+39+58)	GUU GUA AGU UGU CUC CUC UU
155	H39A(+102+121)	UUG UCU GUA ACA GCU GCU GU
156	H39D(+10-10)	GCU CUA AUA CCU UGA GAG CA
157	H40A(-05+17)	CUU UGA GAC CUC AAA UCC UGU U
158	H40A(+129+153)	CUU UAU UUU CCU UUC AUC UCU GGG C
159	H42A(-04+23)	AUC GUU UCU UCA CGG ACA GUG UGC UGG
160	H42A(+86+109)	GGG CUU GUG AGA CAU GAG UGA UUU
161	H42D(+19-02)	A CCU UCA GAG GAC UCC UCU UGC
162	H43D(+10-15)	UAU GUG UUA CCU ACC CUU GUC GGU C
163	H43A(+101+120)	GGA GAG AGC UUC CUG UAG CU
164	H43A(+78+100)	UCA CCC UUU CCA CAG GCG UUG CA
165	H44A(+85+104)	UUU GUG UCU UUC UGA GAA AC
166	H44D(+10-10)	AAA GAC UUA CCU UAA GAU AC
167	H44A(-06+14)	AUC UGU CAA AUC GCC UGC AG
168	H46D(+16-04)	UUA CCU UGA CUU GCU CAA GC

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
169	H46A(+90+109)	UCC AGG UUC AAG UGG GAU AC
170	H47A(+76+100)	GCU CUU CUG GGC UUA UGG GAG CAC U
171	H47D(+25-02)	ACC UUU AUC CAC UGG AGA UUU GUC UGC
172	H47A(-9+12)	UUC CAC CAG UAA CUG AAA CAG
173	H50A(+02+30)	CCA CUC AGA GCU CAG AUC UUC UAA CUU CC
174	H50A(+07+33)	CUU CCA CUC AGA GCU CAG AUC UUC UAA
175	H50D(+07-18)	GGG AUC CAG UAU ACU UAC AGG CUC C
176	H51A(-01+25)	ACC AGA GUA ACA GUC UGA GUA GGA GC
177	H51D(+16-07)	CUC AUA CCU UCU GCU UGA UGA UC
178	H51A(+111 +134)	UUC UGU CCA AGC CCG GUU GAA AUC
179	H51A(+61+90)	ACA UCA AGG AAG AUG GCA UUU CUA GUU UGG
180	H51A(+66+90)	ACA UCA AGG AAG AUG GCA UUU CUA G
181	H51A(+66+95)	CUC CAA CAU CAA GGA AGA UGG CAU UUC UAG
182	H51D(+08-17)	AUC AUU UUU UCU CAU ACC UUC UGC U
183	H51A/D(+08-17) & (-15+)	AUC AUU UUU UCU CAU ACC UUC UGC UAG GAG CUA AAA
184	H51A(+175+195)	CAC CCA CCA UCA CCC UCU GUG
185	H51A(+199+220)	AUC AUC UCG UUG AUA UCC UCA A
186	H52A(-07+14)	UCC UGC AUU GUU GCC UGU AAG
187	H52A(+12+41)	UCC AAC UGG GGA CGC CUC UGU UCC AAA UCC
188	H52A(+17+37)	ACU GGG GAC GCC UCU GUU CCA
189	H52A(+93+112)	CCG UAA UGA UUG UUC UAG CC
190	H52D(+05-15)	UGU UAA AAA ACU UAC UUC GA
191	H53A(+45+69)	CAU UCA ACU GUU GCC UCC GGU UCU G
192	H53A(+39+62)	CUG UUG CCU CCG GUU CUG AAG GUG
193	H53A(+39+69)	CAU UCA ACU GUU GCC UCC GGU UCU GAA GGU G
194	H53D(+14-07)	UAC UAA CCU UGG UUU CUG UGA
195	H53A(+23+47)	CUG AAG GUG UUC UUG UAC UUC AUC C
196	H53A(+150+176)	UGU AUA GGG ACC CUC CUU CCA UGA CUC
197	H53D(+20-05)	CUA ACC UUG GUU UCU GUG AUU UUC U
198	H53D(+09-18)	GGU AUC UUU GAU ACU AAC CUU GGU UUC
199	H53A(-12+10)	AUU CUU UCA ACU AGA AUA AAA G
200	H53A(-07+18)	GAU UCU GAA UUC UUU CAA CUA GAA U
201	H53A(+07+26)	AUC CCA CUG AUU CUG AAU UC
202	H53A(+124+145)	UUG GCU CUG GCC UGU CCU AAG A
203	H46A(+86+115)	CUC UUU UCC AGG UUC AAG UGG GAU ACU AGC

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5' - 3')
204	H46A(+107+137)	CAA GCU UUU CUU UUA GUU GCU GCU CUU UUC C
205	H46A(-10+20)	UAU UCU UUU GUU CUU CUA GCC UGG AGA AAG
206	H46A(+50+77)	CUG CUU CCU CCA ACC AUA AAA CAA AUU C
207	H45A(-06+20)	CCA AUG CCA UCC UGG AGU UCC UGU AA
208	H45A(+91 +110)	UCC UGU AGA AUA CUG GCA UC
209	H45A(+125+151)	UGC AGA CCU CCU GCC ACC GCA GAU UCA
210	H45D(+16 -04)	CUA CCU CUU UUU UCU GUC UG
211	H45A(+71+90)	UGU UUU UGA GGA UUG CUG AA

Table 1A: Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T".

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5'-3')
81 82	H20A(+44+71) H20A(+147+168)	CUG GCA GAA UUC GAU CCA CCG GCU GUU C CAG CAG UAG UUG UCA UCU GCU C
80 81 82	H19A(+35+65) H20A(+44+71) H20A(+147+168)	GCC UGA GCU GAU CUG CUG GCA UCU UGC AGU U CUG GCA GAA UUC GAU CCA CCG GCU GUU C CAG CAG UAG UUG UCA UCU GCU C
194 195 196	H53D(+14-07) H53A(+23+47) H53A(+150+175)	UAC UAA CCU UGG UUU CUG UGA CUG AAG GUG UUC UUG UAC UUC AUC C UGU AUA GGG ACC CUC CUU CCA UGA CUC

Table 1B: Description of a cocktail of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA.

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5'-3')
81 82	H20A(+44+71)- H20A(+147+168)	CUG GCA GAA UUC GAU CCA CCG GCU GUU C- CAG CAG UAG UUG UCA UCU GCU C

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5'-3')
80	H19A(+35+65)-	GCC UGA GCU GAU CUG CUG GCA UCU UGC AGU U
88	H20A(+44+63)-	-AUU CGA UCC ACC GGC UGU UC-
79	H20A(+149+168)	CUG CUG GCA UCU UGC AGU U
80	H19A(+35+65)-	GCC UGA GCU GAU CUG CUG GCA UCU UGC AGU U
88	H20A(+44+63)	-AUU CGA UCC ACC GGC UGU UC-
80	H19A(+35+65)-	GCC UGA GCU GAU CUG CUG GCA UCU UGC AGU U
79	H20A(+149+168)	-CUG CUG GCA UCU UGC AGU U
138	H34A(+46+70)-	CAU UCA UUU CCU UUC GCA UCU UAC G-
139	H34A(+94+120)	UGA UCU CUU UGU CAA UUC CAU AUC UG
124	H31D(+03-22)-	UAG UUU CUG AAA UAA CAU AUA CCU G-
	UU-	UU-
144	H35A(+24+43)	UCU UCA GGU GCA CCU UCU GU
195	H53A(+23+47)-	CUG AAG GUG UUC UUG UAC UUC AUC C-
	AA-	
196	H53A(+150+175)-	UGU AUA GGG ACC CUC CUU CCA UGA CUC-
	AA-	AA-
194	H53D(+14-07)	UAC UAA CCU UGG UUU CUG UGA
- 212	Aimed at exons 19/20/20	CAG CAG UAG UUG UCA UCU GCU CAA CUG GCA GAA UUC GAU CCA CCG GCU GUU CAA GCC UGA GCU GAU CUG CUC GCA UCU UGC AGU

Table 1C: Description of a "weasel" of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA.

DETAILED DESCRIPTION OF THE INVENTION

5 General

Those skilled in the art will appreciate that the invention described herein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention includes all such variation and modifications. The invention also includes all of the steps, features, compositions and compounds referred to

or indicated in the specification, individually or collectively and any and all combinations or any two or more of the steps or features.

The present invention is not to be limited in scope by the specific embodiments described herein, which are intended for the purpose of exemplification only.

- 5 Functionally equivalent products, compositions and methods are clearly within the scope of the invention as described herein.

Sequence identity numbers (SEQ ID NO:) containing nucleotide and amino acid sequence information included in this specification are collected at the end of the description and have been prepared using the programme Patentln Version 3.0. Each
10 nucleotide or amino acid sequence is identified in the sequence listing by the numeric indicator <210> followed by the sequence identifier (e.g. <210>1, <210>2, etc.). The length, type of sequence and source organism for each nucleotide or amino acid sequence are indicated by information provided in the numeric indicator fields <211>, <212> and <213>, respectively. Nucleotide and amino acid sequences referred to in the specification
15 are defined by the information provided in numeric indicator field <400> followed by the sequence identifier (e.g. <400>1, <400>2, etc.).

An antisense molecules nomenclature system was proposed and published to distinguish between the different antisense molecules (see Mann *et al.*, (2002) J Gen Med 4, 644-654). This nomenclature became especially relevant when testing several
20 slightly different antisense molecules, all directed at the same target region, as shown below:

H # A/D (x : y).

The first letter designates the species (e.g. H: human, M: murine, C: canine) "#" designates target dystrophin exon number.

- 25 "A/D" indicates acceptor or donor splice site at the beginning and end of the exon, respectively.

(x y) represents the annealing coordinates where "-" or "+" indicate intronic or exonic sequences respectively. As an example, A(-6+18) would indicate the last 6 bases of the intron preceding the target exon and the first 18 bases of the target exon. The closest

splice site would be the acceptor so these coordinates would be preceded with an "A".

Describing annealing coordinates at the donor splice site could be D(+2-18) where the last 2 exonic bases and the first 18 intronic bases correspond to the annealing site of the antisense molecule. Entirely exonic annealing coordinates that would be represented by

5 A(+65+85), that is the site between the 65th and 85th nucleotide from the start of that exon.

The entire disclosures of all publications (including patents, patent applications, journal articles, laboratory manuals, books, or other documents) cited herein are hereby incorporated by reference. No admission is made that any of the references constitute prior art or are part of the common general knowledge of those working in the
10 field to which this invention relates.

As used necessarily herein the term "derived" and "derived from" shall be taken to indicate that a specific integer may be obtained from a particular source *albeit* not directly from that source.

Throughout this specification, unless the context requires otherwise, the
15 word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

Other definitions for selected terms used herein may be found within the detailed description of the invention and apply throughout. Unless otherwise defined, all
20 other scientific and technical terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which the invention belongs.

DESCRIPTION OF THE PREFERRED EMBODIMENT

When antisense molecule(s) are targeted to nucleotide sequences involved in splicing in exons within pre-mRNA sequences, normal splicing of the exon may be
25 inhibited causing the splicing machinery to by-pass the entire mutated exon from the mature mRNA. The concept of antisense oligonucleotide induced exon skipping is shown in Figure 2. In many genes, deletion of an entire exon would lead to the production of a non-functional protein through the loss of important functional domains or the disruption of

the reading frame. In some proteins, however, it is possible to shorten the protein by deleting one or more exons, without disrupting the reading frame, from within the protein without seriously altering the biological activity of the protein. Typically, such proteins have a structural role and or possess functional domains at their ends. The present invention describes antisense molecules capable of binding to specified dystrophin pre-mRNA targets and re-directing processing of that gene.

Antisense Molecules

According to a first aspect of the invention, there is provided antisense molecules capable of binding to a selected target to induce exon skipping. To induce exon skipping in exons of the Dystrophin gene transcript, the antisense molecules are preferably selected from the group of compounds shown in Table 1A. There is also provided a combination or "cocktail" of two or more antisense oligonucleotides capable of binding to a selected target to induce exon skipping. To induce exon skipping in exons of the Dystrophin gene transcript, the antisense molecules in a "cocktail" are preferably selected from the group of compounds shown in Table 1B. Alternatively, exon skipping may be induced by antisense oligonucleotides joined together "weasels" preferably selected from the group of compounds shown in Table 1C.

Designing antisense molecules to completely mask consensus splice sites may not necessarily generate any skipping of the targeted exon. Furthermore, the inventors have discovered that size or length of the antisense oligonucleotide itself is not always a primary factor when designing antisense molecules. With some targets such as exon 19, antisense oligonucleotides as short as 12 bases were able to induce exon skipping, *albeit* not as efficiently as longer (20-31 bases) oligonucleotides. In some other targets, such as murine dystrophin exon 23, antisense oligonucleotides only 17 residues long were able to induce more efficient skipping than another overlapping compound of 25 nucleotides.

The inventors have also discovered that there does not appear to be any standard motif that can be blocked or masked by antisense molecules to redirect splicing. In some exons, such as mouse dystrophin exon 23, the donor splice site was the most

amenable to target to re-direct skipping of that exon. It should be noted that designing and testing a series of exon 23 specific antisense molecules to anneal to overlapping regions of the donor splice site showed considerable variation in the efficacy of induced exon skipping. As reported in Mann *et al.*, (2002) there was a significant variation in the efficiency of bypassing the nonsense mutation depending upon antisense oligonucleotide annealing ("Improved antisense oligonucleotide induced exon skipping in the *mdx* mouse model of muscular dystrophy". J Gen Med 4: 644-654). Targeting the acceptor site of exon 23 or several internal domains was not found to induce any consistent exon 23 skipping.

In other exons targeted for removal, masking the donor splice site did not induce any exon skipping. However, by directing antisense molecules to the acceptor splice site (human exon 8 as discussed below), strong and sustained exon skipping was induced. It should be noted that removal of human exon 8 was tightly linked with the co-removal of exon 9. There is no strong sequence homology between the exon 8 antisense oligonucleotides and corresponding regions of exon 9 so it does not appear to be a matter of cross reaction. Rather the splicing of these two exons is inextricably linked. This is not an isolated instance as the same effect is observed in canine cells where targeting exon 8 for removal also resulted in the skipping of exon 9. Targeting exon 23 for removal in the mouse dystrophin pre-mRNA also results in the frequent removal of exon 22 as well. This effect occurs in a dose dependent manner and also indicates close coordinated processing of 2 adjacent exons.

In other targeted exons, antisense molecules directed at the donor or acceptor splice sites did not induce exon skipping while annealing antisense molecules to intra-exonic regions (*i.e.* exon splicing enhancers within human dystrophin exon 6) was most efficient at inducing exon skipping. Some exons, both mouse and human exon 19 for example, are readily skipped by targeting antisense molecules to a variety of motifs. That is, targeted exon skipping is induced after using antisense oligonucleotides to mask donor and acceptor splice sites or exon splicing enhancers.

To identify and select antisense oligonucleotides suitable for use in the modulation of exon skipping, a nucleic acid sequence whose function is to be modulated must first be identified. This may be, for example, a gene (or mRNA transcribed from the gene) whose expression is associated with a particular disorder or disease state, or a nucleic acid molecule from an infectious agent. Within the context of the present invention, preferred target site(s) are those involved in mRNA splicing (*i.e.* splice donor sites, splice acceptor sites, or exonic splicing enhancer elements). Splicing branch points and exon recognition sequences or splice enhancers are also potential target sites for modulation of mRNA splicing.

Preferably, the present invention aims to provide antisense molecules capable of binding to a selected target in the dystrophin pre-mRNA to induce efficient and consistent exon skipping. Duchenne muscular dystrophy arises from mutations that preclude the synthesis of a functional dystrophin gene product. These Duchenne muscular dystrophy gene defects are typically nonsense mutations or genomic rearrangements such as deletions, duplications or micro-deletions or insertions that disrupt the reading frame. As the human dystrophin gene is a large and complex gene with the 79 exons being spliced together to generate a mature mRNA with an open reading frame of approximately 11,000 bases, there are many positions where these mutations can occur. Consequently, a comprehensive antisense oligonucleotide based therapy to address many of the different disease-causing mutations in the dystrophin gene will require that many exons can be targeted for removal during the splicing process.

Within the context of the present invention, preferred target site(s) are those involved in mRNA splicing (*i.e.* splice donor sites, splice acceptor sites or exonic splicing enhancer elements). Splicing branch points and exon recognition sequences or splice enhancers are also potential target sites for modulation of mRNA splicing.

The oligonucleotide and the DNA or RNA are complementary to each other when a sufficient number of corresponding positions in each molecule are occupied by nucleotides which can hydrogen bond with each other. Thus, "specifically hybridisable" and "complementary" are terms which are used to indicate a sufficient degree of

complementarity or precise pairing such that stable and specific binding occurs between the oligonucleotide and the DNA or RNA target. It is understood in the art that the sequence of an antisense molecule need not be 100% complementary to that of its target sequence to be specifically hybridisable. An antisense molecule is specifically hybridisable when
5 binding of the compound to the target DNA or RNA molecule interferes with the normal function of the target DNA or RNA to cause a loss of utility, and there is a sufficient degree of complementarity to avoid non-specific binding of the antisense compound to non-target sequences under conditions in which specific binding is desired, *i.e.*, under physiological conditions in the case of *in vivo* assays or therapeutic treatment, and in the
10 case of *in vitro* assays, under conditions in which the assays are performed.

While the above method may be used to select antisense molecules capable of deleting any exon from within a protein that is capable of being shortened without affecting its biological function, the exon deletion should not lead to a reading frame shift in the shortened transcribed mRNA. Thus, if in a linear sequence of three exons the end of
15 the first exon encodes two of three nucleotides in a codon and the next exon is deleted then the third exon in the linear sequence must start with a single nucleotide that is capable of completing the nucleotide triplet for a codon. If the third exon does not commence with a single nucleotide there will be a reading frame shift that would lead to the generation of truncated or a non-functional protein.

20 It will be appreciated that the codon arrangements at the end of exons in structural proteins may not always break at the end of a codon, consequently there may be a need to delete more than one exon from the pre-mRNA to ensure in-frame reading of the mRNA. In such circumstances, a plurality of antisense oligonucleotides may need to be selected by the method of the invention wherein each is directed to a different region
25 responsible for inducing splicing in the exons that are to be deleted.

The length of an antisense molecule may vary so long as it is capable of binding selectively to the intended location within the pre-mRNA molecule. The length of such sequences can be determined in accordance with selection procedures described herein. Generally, the antisense molecule will be from about 10 nucleotides in length up to

about 50 nucleotides in length. It will be appreciated however that any length of nucleotides within this range may be used in the method. Preferably, the length of the antisense molecule is between 17 to 30 nucleotides in length.

In order to determine which exons can be connected in a dystrophin gene, reference should be made to an exon boundary map. Connection of one exon with another is based on the exons possessing the same number at the 3' border as is present at the 5' border of the exon to which it is being connected. Therefore, if exon 7 were deleted, exon 6 must connect to either exons 12 or 18 to maintain the reading frame. Thus, antisense oligonucleotides would need to be selected which redirected splicing for exons 7 to 11 in the first instance or exons 7 to 17 in the second instance. Another and somewhat simpler approach to restore the reading frame around an exon 7 deletion would be to remove the two flanking exons. Induction of exons 6 and 8 skipping should result in an in-frame transcript with the splicing of exons 5 to 9. In practise however, targeting exon 8 for removal from the pre-mRNA results in the co-removal of exon 9 so the resultant transcript would have exon 5 joined to exon 10. The inclusion or exclusion of exon 9 does not alter the reading frame. Once the antisense molecules to be tested have been identified, they are prepared according to standard techniques known in the art. The most common method for producing antisense molecules is the methylation of the 2' hydroxyribose position and the incorporation of a phosphorothioate backbone produces molecules that superficially resemble RNA but that are much more resistant to nuclease degradation.

To avoid degradation of pre-mRNA during duplex formation with the antisense molecules, the antisense molecules used in the method may be adapted to minimise or prevent cleavage by endogenous RNase H. This property is highly preferred as the treatment of the RNA with the unmethylated oligonucleotides either intracellularly or in crude extracts that contain RNase H leads to degradation of the pre-mRNA: antisense oligonucleotide duplexes. Any form of modified antisense molecules that is capable of bypassing or not inducing such degradation may be used in the present method. An example of antisense molecules which when duplexed with RNA are not cleaved by cellular RNase H is 2'-O-methyl derivatives. 2'-O-methyl-oligoribonucleotides are very stable in a cellular

environment and in animal tissues, and their duplexes with RNA have higher T_m values than their ribo- or deoxyribo- counterparts.

Antisense molecules that do not activate RNase H can be made in accordance with known techniques (*see, e.g.*, U.S. Pat. 5,149,797). Such antisense
5 molecules, which may be deoxyribonucleotide or ribonucleotide sequences, simply contain any structural modification which sterically hinders or prevents binding of RNase H to a duplex molecule containing the oligonucleotide as one member thereof, which structural modification does not substantially hinder or disrupt duplex formation. Because the portions of the oligonucleotide involved in duplex formation are substantially different
10 from those portions involved in RNase H binding thereto, numerous antisense molecules that do not activate RNase H are available. For example, such antisense molecules may be oligonucleotides wherein at least one, or all, of the inter-nucleotide bridging phosphate residues are modified phosphates, such as methyl phosphonates, methyl phosphorothioates, phosphoromorpholidates, phosphoropiperazidates and phosphoramidates. For example,
15 every other one of the internucleotide bridging phosphate residues may be modified as described. In another non-limiting example, such antisense molecules are molecules wherein at least one, or all, of the nucleotides contain a 2' lower alkyl moiety (*e.g.*, C_1 - C_4 , linear or branched, saturated or unsaturated alkyl, such as methyl, ethyl, ethenyl, propyl, 1-propenyl, 2-propenyl, and isopropyl). For example, every other one of the nucleotides may
20 be modified as described.

While antisense oligonucleotides are a preferred form of the antisense molecules, the present invention comprehends other oligomeric antisense molecules, including but not limited to oligonucleotide mimetics such as are described below.

Specific examples of preferred antisense compounds useful in this invention
25 include oligonucleotides containing modified backbones or non-natural inter-nucleoside linkages. As defined in this specification, oligonucleotides having modified backbones include those that retain a phosphorus atom in the backbone and those that do not have a phosphorus atom in the backbone. For the purposes of this specification, and as sometimes

referenced in the art, modified oligonucleotides that do not have a phosphorus atom in their inter-nucleoside backbone can also be considered to be oligonucleosides.

In other preferred oligonucleotide mimetics, both the sugar and the inter-nucleoside linkage, *i.e.*, the backbone, of the nucleotide units are replaced with novel groups. The base units are maintained for hybridization with an appropriate nucleic acid target compound. One such oligomeric compound, an oligonucleotide mimetic that has been shown to have excellent hybridization properties, is referred to as a peptide nucleic acid (PNA). In PNA compounds, the sugar-backbone of an oligonucleotide is replaced with an amide containing backbone, in particular an aminoethylglycine backbone. The nucleobases are retained and are bound directly or indirectly to aza nitrogen atoms of the amide portion of the backbone.

Modified oligonucleotides may also contain one or more substituted sugar moieties. Oligonucleotides may also include nucleobase (often referred to in the art simply as "base") modifications or substitutions. Certain nucleobases are particularly useful for increasing the binding affinity of the oligomeric compounds of the invention. These include 5-substituted pyrimidines, 6-azapyrimidines and N-2, N-6 and O-6 substituted purines, including 2-aminopropyladenine, 5-propynyluracil and 5-propynylcytosine. 5-methylcytosine substitutions have been shown to increase nucleic acid duplex stability by 0.6-1.2°C and are presently preferred base substitutions, even more particularly when combined with 2'-O-methoxyethyl sugar modifications.

Another modification of the oligonucleotides of the invention involves chemically linking to the oligonucleotide one or more moieties or conjugates that enhance the activity, cellular distribution or cellular uptake of the oligonucleotide. Such moieties include but are not limited to lipid moieties such as a cholesterol moiety, cholic acid, a thioether, *e.g.*, hexyl-S-tritylthiol, a thiocholesterol, an aliphatic chain, *e.g.*, dodecandiol or undecyl residues, a phospholipid, *e.g.*, di-hexadecyl-rac-glycerol or triethylammonium 1,2-di-O-hexadecyl-rac-glycero-3-H-phosphonate, a polyamine or a polyethylene glycol chain, or adamantane acetic acid, a palmityl moiety, or an octadecylamine or hexylamino-carbonyl-oxycholesterol moiety.

It is not necessary for all positions in a given compound to be uniformly modified, and in fact more than one of the aforementioned modifications may be incorporated in a single compound or even at a single nucleoside within an oligonucleotide. The present invention also includes antisense compounds that are chimeric compounds.

5 "Chimeric" antisense compounds or "chimeras," in the context of this invention, are antisense molecules, particularly oligonucleotides, which contain two or more chemically distinct regions, each made up of at least one monomer unit, *i.e.*, a nucleotide in the case of an oligonucleotide compound. These oligonucleotides typically contain at least one region wherein the oligonucleotide is modified so as to confer upon the increased resistance to
10 nuclease degradation, increased cellular uptake, and an additional region for increased binding affinity for the target nucleic acid.

Methods of Manufacturing Antisense Molecules

The antisense molecules used in accordance with this invention may be conveniently and routinely made through the well-known technique of solid phase
15 synthesis. Equipment for such synthesis is sold by several vendors including, for example, Applied Biosystems (Foster City, Calif.). One method for synthesising oligonucleotides on a modified solid support is described in U.S. Pat. No. 4,458,066.

Any other means for such synthesis known in the art may additionally or alternatively be employed. It is well known to use similar techniques to prepare
20 oligonucleotides such as the phosphorothioates ~ and alkylated derivatives. In one such automated embodiment, diethyl-phosphoramidites are used as starting materials and may be synthesized as described by Beaucage, *et al.*, (1981) *Tetrahedron Letters*, 22:1859-1862.

The antisense molecules of the invention are synthesised *in vitro* and do not include antisense compositions of biological origin, or genetic vector constructs designed
25 to direct the *in vivo* synthesis of antisense molecules. The molecules of the invention may also be mixed, encapsulated, conjugated or otherwise associated with other molecules, molecule structures or mixtures of compounds, as for example, liposomes, receptor

targeted molecules, oral, rectal, topical or other formulations, for assisting in uptake, distribution and/or absorption.

Therapeutic Agents

5 The present invention also can be used as a prophylactic or therapeutic, which may be utilised for the purpose of treatment of a genetic disease.

Accordingly, in one embodiment the present invention provides antisense molecules that bind to a selected target in the dystrophin pre-mRNA to induce efficient and consistent exon skipping described herein in a therapeutically effective amount admixed with a pharmaceutically acceptable carrier, diluent, or excipient.

10 The phrase "pharmaceutically acceptable" refers to molecular entities and compositions that are physiologically tolerable and do not typically produce an allergic or similarly untoward reaction, such as gastric upset and the like, when administered to a patient. The term "carrier" refers to a diluent, adjuvant, excipient, or vehicle with which the compound is administered. Such pharmaceutical carriers can be sterile liquids, such as
15 water and oils, including those of petroleum, animal, vegetable or synthetic origin, such as peanut oil, soybean oil, mineral oil, sesame oil and the like. Water or saline solutions and aqueous dextrose and glycerol solutions are preferably employed as carriers, particularly for injectable solutions. Suitable pharmaceutical carriers are described in Martin, *Remington's Pharmaceutical Sciences*, 18th Ed., Mack Publishing Co., Easton, PA, (1990).

20 In a more specific form of the invention there are provided pharmaceutical compositions comprising therapeutically effective amounts of an antisense molecule together with pharmaceutically acceptable diluents, preservatives, solubilizers, emulsifiers, adjuvants and/or carriers. Such compositions include diluents of various buffer content (*e.g.*, Tris-HCl, acetate, phosphate), pH and ionic strength and additives such as detergents
25 and solubilizing agents (*e.g.*, Tween 80, Polysorbate 80), anti-oxidants (*e.g.*, ascorbic acid, sodium metabisulfite), preservatives (*e.g.*, Thimersol, benzyl alcohol) and bulking substances (*e.g.*, lactose, mannitol). The material may be incorporated into particulate preparations of polymeric compounds such as polylactic acid, polyglycolic acid, etc. or into

liposomes. Hylauronic acid may also be used. Such compositions may influence the physical state, stability, rate of *in vivo* release, and rate of *in vivo* clearance of the present proteins and derivatives. *See, e.g., Martin, Remington's Pharmaceutical Sciences*, 18th Ed. (1990, Mack Publishing Co., Easton, PA 18042) pages 1435-1712 that are herein

5 incorporated by reference. The compositions may be prepared in liquid form, or may be in dried powder, such as lyophilised form.

It will be appreciated that pharmaceutical compositions provided according to the present invention may be administered by any means known in the art. Preferably, the pharmaceutical compositions for administration are administered by injection, orally, or
10 by the pulmonary, or nasal route. The antisense molecules are more preferably delivered by intravenous, intra-arterial, intraperitoneal, intramuscular, or subcutaneous routes of administration.

Antisense molecule based therapy

Also addressed by the present invention is the use of antisense molecules of
15 the present invention, for manufacture of a medicament for modulation of a genetic disease.

The delivery of a therapeutically useful amount of antisense molecules may be achieved by methods previously published. For example, intracellular delivery of the antisense molecule may be via a composition comprising an admixture of the antisense
20 molecule and an effective amount of a block copolymer. An example of this method is described in US patent application US 20040248833.

Other methods of delivery of antisense molecules to the nucleus are described in Mann CJ *et al.*, (2001) ["*Antisense-induced exon skipping and the synthesis of dystrophin in the mdx mouse*". *Proc., Natl. Acad. Science*, 98(1) 42-47J and in Gebiski
25 *et al.*, (2003). *Human Molecular Genetics*, 12(15): 1801-1811.

A method for introducing a nucleic acid molecule into a cell by way of an expression vector either as naked DNA or complexed to lipid carriers, is described in US patent US 6,806,084.

It may be desirable to deliver the antisense molecule in a colloidal dispersion system. Colloidal dispersion systems include macromolecule complexes, nanocapsules, microspheres, beads, and lipid-based systems including oil-in-water emulsions, micelles, mixed micelles, and liposomes or liposome formulations.

5 Liposomes are artificial membrane vesicles which are useful as delivery vehicles *in vitro* and *in vivo*. These formulations may have net cationic, anionic or neutral charge characteristics and are useful characteristics with *in vitro*, *in vivo* and *ex vivo* delivery methods. It has been shown that large unilamellar vesicles (LUV), which range in size from 0.2-4.0 μ m can encapsulate a substantial percentage of an aqueous buffer
10 containing large macromolecules. RNA, and DNA can be encapsulated within the aqueous interior and be delivered to cells in a biologically active form (Fraley, *et al.*, Trends Biochem. Sci., 6:77, 1981).

In order for a liposome to be an efficient gene transfer vehicle, the following characteristics should be present: (1) encapsulation of the antisense molecule of interest at
15 high efficiency while not compromising their biological activity; (2) preferential and substantial binding to a target cell in comparison to non-target cells; (3) delivery of the aqueous contents of the vesicle to the target cell cytoplasm at high efficiency; and (4) accurate and effective expression of genetic information (Mannino, *et al.*, Biotechniques, 6:682, 1988).

20 The composition of the liposome is usually a combination of phospholipids, particularly high-phase-transition-temperature phospholipids, usually in combination with steroids, especially cholesterol. Other phospholipids or other lipids may also be used. The physical characteristics of liposomes depend on pH, ionic strength, and the presence of divalent cations.

25 Alternatively, the antisense construct may be combined with other pharmaceutically acceptable carriers or diluents to produce a pharmaceutical composition. Suitable carriers and diluents include isotonic saline solutions, for example phosphate-buffered saline. The composition may be formulated for parenteral, intramuscular, intravenous, subcutaneous, intraocular, oral or transdermal administration.

The routes of administration described are intended only as a guide since a skilled practitioner will be able to determine readily the optimum route of administration and any dosage for any particular animal and condition. Multiple approaches for introducing functional new genetic material into cells, both *in vitro* and *in vivo* have been attempted (Friedmann (1989) Science, 244:1275-1280).

These approaches include integration of the gene to be expressed into modified retroviruses (Friedmann (1989) supra; Rosenberg (1991) Cancer Research 51(18), suppl.: 5074S-5079S); integration into non-retrovirus vectors (Rosenfeld, *et al.* (1992) Cell, 68:143-155; Rosenfeld, *et al.* (1991) Science, 252:431-434); or delivery of a transgene linked to a heterologous promoter-enhancer element via liposomes (Friedmann (1989), supra; Brigham, *et al.* (1989) Am. J. Med. Sci., 298:278-281; Nabel, *et al.* (1990) Science, 249:1285-1288; Hazinski, *et al.* (1991) Am. J. Resp. Cell Molec. Biol., 4:206-209; and Wang and Huang (1987) Proc. Natl. Acad. Sci. (USA), 84:7851-7855); coupled to ligand-specific, cation-based transport systems (Wu and Wu (1988) J. Biol. Chem., 263:14621-14624) or the use of naked DNA, expression vectors (Nabel *et al.* (1990), supra); Wolff *et al.* (1990) Science, 247:1465-1468). Direct injection of transgenes into tissue produces only localized expression (Rosenfeld (1992) supra; Rosenfeld *et al.* (1991) supra; Brigham *et al.* (1989) supra; Nabel (1990) supra; and Hazinski *et al.* (1991) supra). The Brigham *et al.* group (Am. J. Med. Sci. (1989) 298:278-281 and Clinical Research (1991) 39 (abstract)) have reported *in vivo* transfection only of lungs of mice following either intravenous or intratracheal administration of a DNA liposome complex. An example of a review article of human gene therapy procedures is: Anderson, Science (1992) 256:808-813.

The antisense molecules of the invention encompass any pharmaceutically acceptable salts, esters, or salts of such esters, or any other compound which, upon administration to an animal including a human, is capable of providing (directly or indirectly) the biologically active metabolite or residue thereof. Accordingly, for example, the disclosure is also drawn to prodrugs and pharmaceutically acceptable salts of the

compounds of the invention, pharmaceutically acceptable salts of such pro-drugs, and other bioequivalents.

The term "pharmaceutically acceptable salts" refers to physiologically and pharmaceutically acceptable salts of the compounds of the invention: *i.e.*, salts that retain
5 the desired biological activity of the parent compound and do not impart undesired toxicological effects thereto.

For oligonucleotides, preferred examples of pharmaceutically acceptable salts include but are not limited to (a) salts formed with cations such as sodium, potassium, ammonium, magnesium, calcium, polyamines such as spermine and spermidine, etc.; (b)
10 acid addition salts formed with inorganic acids, for example hydrochloric acid, hydrobromic acid, sulfuric acid, phosphoric acid, nitric acid and the like; (c) salts formed with organic acids such as, for example, acetic acid, oxalic acid, tartaric acid, succinic acid, malefic acid, fumaric acid, gluconic acid, citric acid, malic acid, ascorbic acid, benzoic acid, tannic acid, palmitic acid, alginic acid, polyglutamic acid, naphthalenesulfonic acid,
15 methanesulfonic acid, p-toluenesulfonic acid, naphthalenedisulfonic acid, polygalacturonic acid, and the like; and (d) salts formed from elemental anions such as chlorine, bromine, and iodine. The pharmaceutical compositions of the present invention may be administered in a number of ways depending upon whether local or systemic treatment is desired and upon the area to be treated. Administration may be topical (including
20 ophthalmic and to mucous membranes including rectal delivery), pulmonary, *e.g.*, by inhalation or insufflation of powders or aerosols, (including by nebulizer, intratracheal, intranasal, epidermal and transdermal), oral or parenteral. Parenteral administration includes intravenous, intra-arterial, subcutaneous, intraperitoneal or intramuscular injection or infusion; or intracranial, *e.g.*, intrathecal or intraventricular, administration.
25 Oligonucleotides with at least one 2'-O-methoxyethyl modification are believed to be particularly useful for oral administration.

The pharmaceutical formulations of the present invention, which may conveniently be presented in unit dosage form, may be prepared according to conventional techniques well known in the pharmaceutical industry. Such techniques include the step of

bringing into association the active ingredients with the pharmaceutical carrier(s) or excipient(s). In general the formulations are prepared by uniformly and intimately bringing into association the active ingredients with liquid carriers or finely divided solid carriers or both, and then, if necessary, shaping the product.

5 Kits of the Invention

The invention also provides kits for treatment of a patient with a genetic disease which kit comprises at least an antisense molecule, packaged in a suitable container, together with instructions for its use.

In a preferred embodiment, the kits will contain at least one antisense
10 molecule as shown in Table 1A, or a cocktail of antisense molecules as shown in Table 1B or a "weasel" compound as shown in Table 1C. The kits may also contain peripheral reagents such as buffers, stabilizers, etc.

Those of ordinary skill in the field should appreciate that applications of the above method has wide application for identifying antisense molecules suitable for use in
15 the treatment of many other diseases.

EXAMPLES

The following Examples serve to more fully describe the manner of using the above-described invention, as well as to set forth the best modes contemplated for carrying out various aspects of the invention. It is understood that these Examples in no
20 way serve to limit the true scope of this invention, but rather are presented for illustrative purposes. The references cited herein are expressly incorporated by reference.

Methods of molecular cloning, immunology and protein chemistry, which are not explicitly described in the following examples, are reported in the literature and are known by those skilled in the art. General texts that described conventional molecular
25 biology, microbiology, and recombinant DNA techniques within the skill of the art, included, for example: Sambrook *et al*, *Molecular Cloning: A Laboratory Manual*, Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York (1989);

Glover ed., *DNA Cloning: A Practical Approach*, Volumes I and II, MRL Press, Ltd., Oxford, U.K. (1985); and Ausubel, F., Brent, R., Kingston, R.E., Moore, D.D., Seidman, J.G., Smith, J.A., Struhl, K. *Current Protocols in Molecular Biology*. Greene Publishing Associates/Wiley Intersciences, New York (2002).

5 DETERMINING INDUCED EXON SKIPPING IN HUMAN MUSCLE CELLS

Attempts by the inventors to develop a rational approach in antisense molecules design were not completely successful as there did not appear to be a consistent trend that could be applied to all exons. As such, the identification of the most effective and therefore most therapeutic antisense molecules compounds has been the result of
10 empirical studies.

These empirical studies involved the use of computer programs to identify motifs potentially involved in the splicing process. Other computer programs were also used to identify regions of the pre-mRNA which may not have had extensive secondary structure and therefore potential sites for annealing of antisense molecules. Neither of
15 these approaches proved completely reliable in designing antisense oligonucleotides for reliable and efficient induction of exon skipping.

Annealing sites on the human dystrophin pre-mRNA were selected for examination, initially based upon known or predicted motifs or regions involved in splicing. 2OMe antisense oligonucleotides were designed to be complementary to the
20 target sequences under investigation and were synthesised on an Expedite 8909 Nucleic Acid Synthesiser. Upon completion of synthesis, the oligonucleotides were cleaved from the support column and de-protected in ammonium hydroxide before being desalted. The quality of the oligonucleotide synthesis was monitored by the intensity of the trityl signals upon each deprotection step during the synthesis as detected in the synthesis log. The
25 concentration of the antisense oligonucleotide was estimated by measuring the absorbance of a diluted aliquot at 260nm.

Specified amounts of the antisense molecules were then tested for their ability to induce exon skipping in an *in vitro* assay, as described below.

Briefly, normal primary myoblast cultures were prepared from human muscle biopsies obtained after informed consent. The cells were propagated and allowed to differentiate into myotubes using standard culturing techniques. The cells were then transfected with the antisense oligonucleotides by delivery of the oligonucleotides to the
5 dells as cationic lipoplexes, mixtures of antisense molecules or cationic liposome preparations.

The cells were then allowed to grow for another 24 hours, after which total RNA was extracted and molecular analysis commenced. Reverse transcriptase amplification (RT-PCR) was undertaken to study the targeted regions of the dystrophin
10 pre-mRNA or induced exonic re-arrangements.

For example, in the testing of an antisense molecule for inducing exon 19 skipping the RT-PCR test scanned several exons to detect involvement of any adjacent exons. For example, when inducing skipping of exon 19, RT-PCR was carried out with primers that amplified across exons 17 and 21. Amplifications of even larger products in
15 this area (*i.e.* exons 13-26) were also carried out to ensure that there was minimal amplification bias for the shorter induced skipped transcript. Shorter or exon skipped products tend to be amplified more efficiently and may bias the estimated of the normal and induced transcript.

The sizes of the amplification reaction products were estimated on an
20 agarose gel and compared against appropriate size standards. The final confirmation of identity of these products was carried out by direct DNA sequencing to establish that the correct or expected exon junctions have been maintained.

Once efficient exon skipping had been induced with one antisense molecule, subsequent overlapping antisense molecules may be synthesized and then evaluated in the
25 assay as described above. Our definition of an efficient antisense molecule is one that induces strong and sustained exon skipping at transfection concentrations in the order of 300 nM or less.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 8

Antisense oligonucleotides directed at exon 8 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

5 Figure 3 shows differing efficiencies of two antisense molecules directed at exon 8 acceptor splice site. H8A(-06+18) [SEQ ID NO:1], which anneals to the last 6 bases of intron 7 and the first 18 bases of exon 8, induces substantial exon 8 and 9 skipping when delivered into cells at a concentration of 20 nM. The shorter antisense molecule, H8A(-06+14) [SEQ ID NO: 4] was only able to induce exon 8 and 9 skipping at 300 nM, a
10 concentration some 15 fold higher than H8A(-06+18), which is the preferred antisense molecule.

 This data shows that some particular antisense molecules induce efficient exon skipping while another antisense molecule, which targets a near-by or overlapping region, can be much less efficient. Titration studies show one compound is able to induce
15 targeted exon skipping at 20 nM while the less efficient antisense molecules only induced exon skipping at concentrations of 300 nM and above. Therefore, we have shown that targeting of the antisense molecules to motifs involved in the splicing process plays a crucial role in the overall efficacy of that compound.

 Efficacy refers to the ability to induce consistent skipping of a target exon.
20 However, sometimes skipping of the target exons is consistently associated with a flanking exon. That is, we have found that the splicing of some exons is tightly linked. For example, in targeting exon 23 in the mouse model of muscular dystrophy with antisense molecules directed at the donor site of that exon, dystrophin transcripts missing exons 22 and 23 are frequently detected. As another example, when using an antisense molecule
25 directed to exon 8 of the human dystrophin gene, all induced transcripts are missing both exons 8 and 9. Dystrophin transcripts missing only exon 8 are not observed.

 Table 2 below discloses antisense molecule sequences that induce exon 8 (and 9) skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
1	H8A(-06+18)	5'-GAU AGG UGG UAU CAA CAU CUG UAA	Very strong to 20 nM
2	H8A (-03+18)	5'-GAU AGG UGG UAU CAA CAU CUG	Very strong skipping to 40nM
3	H8A(-07+18)	5'-GAU AGG UGG UAU CAA CAU CUG UAA G	Strong skipping to 40nM
4	H8A(-06+14)	5'-GGU GGU AUC AAC AUC UGU AA	Skipping to 300nM
5	H8A(-10+10)	5'-GUA UCA ACA UCU GUA AGC AC	Patchy/weak skipping to 100nm

Table 2

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 7

Antisense oligonucleotides directed at exon 7 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

Figure 4 shows the preferred antisense molecule, H7A(+45+67) [SEQ ID NO: 6], and another antisense molecule, H7A(+2+26) [SEQ ID NO: 7], inducing exon 7 skipping. Nested amplification products span exons 3 to 9. Additional products above the induced transcript missing exon 7 arise from amplification from carry-over outer primers

10 from the RT-PCR as well as heteroduplex formation.

Table 3 below discloses antisense molecule sequences for induced exon 7 skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
6	H7A(+45+67)	5' - UGC AUG UUC CAG UCG UUG UGU GG	Strong skipping to 20nM
7	H7A(+02+26)	5' - CAC UAU UCC AGU CAA AUA GGU CUG G	Weak skipping at 100nM
8	H7D(+15-10)	5' -AUU UAC CAA CCU UCA GGA UCG AGU A	Weak skipping to 300nM
9	H7A(-18+03)	5' - GGC CUA AAA CAC AUA CAC AUA	Weak skipping to 300nM

Table 3

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 6

Antisense oligonucleotides directed at exon 6 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 5 shows an example of two non-preferred antisense molecules inducing very low levels of exon 6 skipping in cultured human cells. Targeting this exon for specific removal was first undertaken during a study of the canine model using the oligonucleotides as listed in Table 4, below. Some of the human specific oligonucleotides were also evaluated, as shown in Figure 5. In this example, both antisense molecules target the donor splice site and only induced low levels of exon 6 skipping. Both H6D(+4-21) [SEQ ID NO: 17] and H6D(+18-4) [SEQ ID NO: 18] would be regarded as non-preferred antisense molecules.

One antisense oligonucleotide that induced very efficient exon 6 skipping in the canine model, C6A(+69+91) [SEQ ID NO: 14], would anneal perfectly to the corresponding region in human dystrophin exon 6. This compound was evaluated, found to be highly efficient at inducing skipping of that target exon, as shown in Figure 6 and is regarded as the preferred compound for induced exon 6 skipping. Table 4 below discloses antisense molecule sequences for induced exon 6 skipping.

SEQ ID	Antisense Oligo name	Sequence	Ability to induce skipping
10	C6A(-10+10)	5' CAU UUU UGA CCU ACA UGU GG	No skipping
11	C6A(-14+06)	5' UUU GAC CUA CAU GUG GAA AG	No skipping
12	C6A(-14+12)	5' UAC AUU UUU GAC CUA CAU GUG GAA AG	No skipping
13	C6A(-13+09)	5' AUU UUU GAC CUA CAU GGG AAA G	No skipping
14	CH6A(+69+91)	5' UAC GAG UUG AUU GUC GGA CCC AG	Strong skipping to 20 nM
15	C6D(+12-13)	5' GUG GUC UCC UUA CCU AUG ACU GUG G	Weak skipping at 300 nM
16	C6D(+06-11)	5' GGU CUC CUU ACC UAU GA	No skipping
17	H6D(+04-21)	5' UGU CUC AGU AAU CUU CUU ACC UAU	Weak skipping to 50 nM
18	H6D(+18-04)	5' UCU UAC CUA UGA CUA UGG AUG AGA	Very weak skipping to 300 nM

Table 4

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 4

Antisense oligonucleotides directed at exon 4 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 7 shows an example of a preferred antisense molecule inducing skipping of exon 4 skipping in cultured human cells. In this example, one preferred antisense compound, H4A(+13+32) [SEQ ID NO:19], which targeted a presumed exonic splicing enhancer induced efficient exon skipping at a concentration of 20 nM while other non-preferred antisense oligonucleotides failed to induce even low levels of exon 4 skipping. Another preferred antisense molecule inducing skipping of exon 4 was H4A(+111+40) [SEQ ID NO:22], which induced efficient exon skipping at a concentration of 20 nM.

Table 5 below discloses antisense molecule sequences for inducing exon 4 skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
19	H4A(+13+32)	5' GCA UGA ACU CUU GUG GAU CC	Skipping to 20 nM
22	H4A(+11+40)	5' UGU UCA GGG CAU GAA CUC UUG UGG AUC CUU	Skipping to 20 nM
20	H4D(+04-16)	5' CCA GGG UAC UAC UUA CAU UA	No skipping
21	H4D(-24-44)	5' AUC GUG UGU CAC AGC AUC CAG	No skipping

Table 5

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 3

Antisense oligonucleotides directed at exon 3 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H3A(+30+60) [SEQ ID NO:23] induced substantial exon 3 skipping when delivered into cells at a concentration of 20 nM to 600 nM. The antisense molecule, H3A(+35+65) [SEQ ID NO: 24] induced exon skipping at 300 nM.

Table 6 below discloses antisense molecule sequences that induce exon 3
10 skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
23	H3A(+30+60)	UAG GAG GCG CCU CCC AUC CUG UAG GUC ACU G	Moderate skipping to 20 to 600 nM
24	H3A(+35+65)	AGG UCU AGG AGG CGC CUC CCA UCC UGU AGG U	Working to 300 nM
25	H3A(+30+54)	GCG CCU CCC AUC CUG UAG GUC ACU G	Moderate 100-600 nM
26	H3D(+46-21)	CUU CGA GGA GGU CUA GGA GGC GCC UC	No skipping
27	H3A(+30+50)	CUC CCA UCC UGU AGG UCA CUG	Moderate 20-600 nM
28	H3D(+19-03)	UAC CAG UUU UUG CCC UGU CAG G	No skipping
29	H3A(-06+20)	UCA AUA UGC UGC UUCCCA AAC UGA AA	No skipping

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
30	H3A(+37+61)	CUA GGA GGC GCC UCC CAU CCU GUA G	No skipping

Table 6

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 5

Antisense oligonucleotides directed at exon 5 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H5A(+20+50) [SEQ ID NO:31] induces substantial exon 5 skipping when delivered into cells at a concentration of 100 nM. Table 7 below shows other antisense molecules tested. The majority of these antisense molecules were not as effective at exon skipping as H5A(+20+50). However, H5A(+15+45) [SEQ ID NO: 40] was able to induce

10 exon 5 skipping at 300 nM.

Table 7 below discloses antisense molecule sequences that induce exon 5 skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
31	H5A(+20+50)	UUA UGA UUU CCA UCU ACG AUG UCA GUA CUU C	Working to 100 nM
32	H5D(+25-05)	CUU ACC UGC CAG UGG AGG AUU AUA UUC CAA A	No skipping
33	H5D(+10-15)	CAU CAG GAU UCU UAC CUG CCA GUG G	Inconsistent at 300 nM
34	H5A(+10+34)	CGA UGU CAG UAC UUC CAA UAU UCA C	Very weak
35	H5D(-04-21)	ACC AUU CAU CAG GAU UCU	No skipping
36	H5D(+16-02)	ACC UGC CAG UGG AGG AUU	No skipping
37	H5A(-07+20)	CCA AUA UUC ACU AAA UCA ACC UGU UAA	No skipping
38	H5D(+18-12)	CAG GAU UCU UAC CUG CCA GUG GAG GAU UAU	No skipping

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
39	H5A(+05+35)	ACG AUG UCA GUA CUU CCA AUA UUC ACU AAA U	No skipping
40	H5A(+15+45)	AUU UCC AUC UAC GAU GUC AGU ACU UCC AAU A	Working to 300 nM

Table 7

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 10

Antisense oligonucleotides directed at exon 10 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H10A(-05+16) [SEQ ID NO:41] induced substantial exon 10 skipping when delivered into cells. Table 8 below shows other antisense molecules tested. The antisense molecules ability to induce exon skipping was variable. Table 8 below discloses antisense molecule sequences that induce exon 10 skipping.

10

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
41	H10A(-05+16)	CAG GAG CUU CCA AAU GCU GCA	Not tested
42	H10A(-05+24)	CUU GUC UUC AGG AGC UUC CAA AUG CUG CA	Not tested
43	H10A(+98+119)	UCC UCA GCA GAA AGA AGC CAC G	Not tested
44	H10A(+130+149)	UUA GAA AUC UCU CCU UGU GC	No skipping
45	H10A(-33-14)	UAA AUU GGG UGU UAC ACA AU	No skipping

Table 8

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 11

Antisense oligonucleotides directed at exon 11 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

15 described above.

Figure 8B shows an example of H11A(+75+97) [SEQ ID NO:49] antisense molecule inducing exon 11 skipping in cultured human cells. H11A(+75+97) induced substantial exon 11 skipping when delivered into cells at a concentration of 5 nM. Table 9

below shows other antisense molecules tested. The antisense molecules ability to induce exon skipping was observed at 100 nM.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
46	H11D(+26+49)	CCC UGA GGC AUU CCC AUC UUG AAU	Skipping at 100 nM
47	H11D(+11-09)	AGG ACU UAC UUG CUU UGU UU	Skipping at 100 nM
48	H11A(+118+140)	CUU GAA UUU AGG AGA UUC AUC UG	Skipping at 100 nM
49	H11A(+75+97)	CAU CUU CUG AUA AUU UUC CUG UU	Skipping at 100 nM
46	H11D(+26+49)	CCC UGA GGC AUU CCC AUC UUG AAU	Skipping at 5nM

Table 9

5 ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 12

Antisense oligonucleotides directed at exon 12 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

H12A(+52+75) [SEQ ID NO:50] induced substantial exon 12 skipping when delivered into cells at a concentration of 5 nM, as shown in Figure 8A. Table 10 below shows other antisense molecules tested at a concentration range of 5, 25, 50, 100, 200 and 300 nM. The antisense molecules ability to induce exon skipping was variable.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
50	H12A(+52+75)	UCU UCU GUU UUU GUU AGC CAG UCA	Skipping at 5 nM
51	H12A(-10+10)	UCU AUG UAA ACU GAA AAU UU	Skipping at 100 nM
52	H12A(+11+30)	UUC UGG AGA UCC AUU AAA AC	No skipping

Table 10

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 13

Antisense oligonucleotides directed at exon 13 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

- 5 H13A(+77+100) [SEQ ID NO:53] induced substantial exon 13 skipping when delivered into cells at a concentration of 5 nM. Table 11 below includes two other antisense molecules tested at a concentration range of 5, 25, 50, 100, 200 and 300 nM. These other antisense molecules were unable to induce exon skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
53	H13A(+77+100)	CAG CAG UUG CGU GAU CUC CAC UAG	Skipping at 5 nM
54	H13A(+55+75)	UUC AUC AAC UAC CAC CAC CAU	No skipping
55	H13D(+06-19)	CUA AGC AAA AUA AUC UGA CCU UAA G	No skipping

10 Table 11

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 14

Antisense oligonucleotides directed at exon 14 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

- 15 H14A(+37+64) [SEQ ID NO:56] induced weak exon 14 skipping when delivered into cells at a concentration of 100 nM. Table 12 below includes other antisense molecules tested at a concentration range of 5, 25, 50, 100, 200 and 300 nM. The other antisense molecules were unable to induce exon skipping at any of the concentrations tested.

20

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
56	H14A(+37+64)	CUU GUA AAA GAA CCC AGC GGU CUU CUG U	Skipping at 100 nM

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
57	H14A(+14+35)	CAU CUA CAG AUG UUU GCC CAU C	No skipping
58	H14A(+51+73)	GAA GGA UGU CUU GUA AAA GAA CC	No skipping
59	H14D(-02+18)	ACC UGU UCU UCA GUA AGA CG	No skipping
60	H14D(+14-10)	CAU GAC ACA CCU GUU CUU CAG UAA	No skipping
61	H14A(+61 +80)	CAU UUG AGA AGG AUG UCU UG	No skipping
62	H14A(-12+12)	AUC UCC CAA UAC CUG GAG AAG AGA	No skipping

Table 12

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 15

Antisense oligonucleotides directed at exon 15 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H15A(-12+19) [SEQ ID NO:63] and H15A(+48+71) [SEQ ID NO:64] induced substantial exon 15 skipping when delivered into cells at a concentration of 10 Nm, as shown in Figure 9A. Table 13 below includes other antisense molecules tested at a concentration range of 5, 25, 50, 100, 200 and 300 Nm. These other antisense molecules
10 were unable to induce exon skipping at any of the concentrations tested.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
63	H15A(-12+19)	GCC AUG CAC UAA AAA GGC ACU GCA AGA CAU U	Skipping at 5Nm
64	H15A(+48+71)	UCU UUA AAG CCA GUU GUG UGA AUC	Skipping at 5Nm
65	H15A(+08+28)	UUU CUG AAA GCC AUG CAC UAA	No skipping
63	H15A(-12+19)	GCC AUG CAC UAA AAA GGC ACU GCA AGA CAU U	No skipping
66	H15D(+17-08)	GUA CAU ACG GCC AGU UUU UGA AGA C	No skipping

Table 13

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 16

Antisense oligonucleotides directed at exon 16 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H16A(-12+19) [SEQ ID NO:67] and H16A(-06+25) [SEQ ID NO:68] induced substantial exon 16 skipping when delivered into cells at a concentration of 10 nM, as shown in Figure 9B. Table 14 below includes other antisense molecules tested. H16A(-06+19) [SEQ ID NO:69] and H16A(+87+109) [SEQ ID NO:70] were tested at a

10 concentration range of 5, 25, 50, 100, 200 and 300 nM. These two antisense molecules were able to induce exon skipping at 25 nM and 100 nM, respectively. Additional antisense molecules were tested at 100, 200 and 300 nM and did not result in any exon skipping.

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
67	H16A(-12+19)	CUA GAU CCG CUU UUA AAA CCU GUU AAA ACA A	Skipping at 5 nM
68	H16A(-06+25)	UCU UUU CUA GAU CCG CUU UUA AAA CCU GUU A	Skipping at 5 nM
69	H16A(-06+19)	CUA GAU CCG CUU UUA AAA CCU GUU A	Skipping at 25 nM
70	H16A(+87+109)	CCG UCU UCU GGG UCA CUG ACU UA	Skipping at 100 nM

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
71	H16A(-07+19)	CUA GAU CCG CUU UUA AAA CCU GUU AA	No skipping
72	H16A(-07+13)	CCG CUU UUA AAA CCU GUU AA	No skipping
73	H16A(+12+37)	UGG AUU GCU UUU UCU UUU CUA GAU CC	No skipping
74	H16A(+92+116)	CAU GCU UCC GUC UUC UGG GUC ACU G	No skipping
75	H16A(+45+67)	G AUC UUG UUU GAG UGA AUA CAG U	No skipping
76	H16A(+105+126)	GUU AUC CAG CCA UGC UUC CGU C	No skipping
77	H16D(+05-20)	UGA UAA UUG GUA UCA CUA ACC UGU G	No skipping
78	H16D(+12-11)	GUA UCA CUA ACC UGU GCU GUA C	No skipping

Table 14

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 19

Antisense oligonucleotides directed at exon 19 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

H19A(+35+65) [SEQ ID NO:79] induced substantial exon 19 skipping when delivered into cells at a concentration of 10 nM. This antisense molecule also showed very strong exon skipping at concentrations of 25, 50, 100, 300 and 600 nM.

Figure 10 illustrates exon 19 and 20 skipping using a "cocktail" of antisense oligonucleotides, as tested using gel electrophoresis. It is interesting to note that it was not easy to induce exon 20 skipping using single antisense oligonucleotides H20A(+44+71) [SEQ ID NO:81] or H20A(+149+170) [SEQ ID NO:82], as illustrated in sections 2 and 3 of the gel shown in Figure 10. Whereas, a "cocktail" of antisense oligonucleotides was more efficient as can be seen in section 4 of Figure 10 using a "cocktail" of antisense oligonucleotides H20A(+44+71) and H20A(+149+170). When the cocktail was used to target exon 19, skipping was even stronger (see section 5, Figure 10).

Figure 11 illustrates gel electrophoresis results of exon 19/20 skipping using "weasels" The "weasels" were effective in skipping exons 19 and 20 at concentrations of 25, 50, 100, 300 and 600 nM. A further "weasel" sequence is shown in the last row of Table 3C. This compound should give good results.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 20

Antisense oligonucleotides directed at exon 20 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

5 None of the antisense oligonucleotides tested induced exon 20 skipping when delivered into cells at a concentration of 10, 25, 50, 300 or 600 nM (see Table 15). Antisense molecules H20A(-11+17) [SEQ ID NO:86] and H20D(+08-20) [SEQ ID NO:87] are yet to be tested.

10 However, a combination or "cocktail" of H20A(+44+71) [SEQ ID NO: 81] and H20(+149+170) [SEQ ID NO:82] in a ratio of 1:1, exhibited very strong exon skipping at a concentration of 100 nM and 600 nM. Further, a combination of antisense molecules H19A(+35+65) [SEQ ID NO:79], H20A(+44+71) [SEQ ID NO:81] and H20A(+149+170) [SEQ ID NO:82] in a ratio of 2:1:1, induced very strong exon skipping at a concentration ranging from 10 nM to 600 nM.

15

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
81	H20A(+44+71)	CUG GCA GAA UUC GAU CCA CCG GCU GUU C	No skipping
82	H20A(+147+168)	CAG CAG UAG UUG UCA UCU GCU C	No skipping
83	H20A(+185+203)	UGA UGG GGU GGU GGG UUG G	No skipping
84	H20A(-08+17)	AUC UGC AUU AAC ACC CUC UAG AAA G	No skipping
85	H20A(+30+53)	CCG GCU GUU CAG UUG UUC UGA GGC	No skipping
86	H20A(-11+17)	AUC UGC AUU AAC ACC CUC UAG AAA GAA A	Not tested yet
87	H20D(+08-20)	GAA GGA GAA GAG AUU CUU ACC UUA CAA A	Not tested yet
81 & 82	H20A(+44+71) & H20A(+147+168)	CUG GCA GAA UUC GAU CCA CCG GCU GUU C CAG CAG UAG UUG UCA UCU GCU C	Very strong skipping
80, 81	H19A(+35+65);	GCC UGA GCU GAU CUG CUG GCA UCU	Very strong

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
& 82	H20A(+44+71); H20A(+147+168)	UGC AGU U; CUG GCA GAA UUC GAU CCA CCG GCU GUU C; CAG CAG UAG UUG UCA UCU GCU C	skipping

Table 15

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 21

Antisense oligonucleotides directed at exon 21 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

H21A(+85+108) [SEQ ID NO:92] and H21A(+85+106) [SEQ ID NO:91] induced exon 21 skipping when delivered into cells at a concentration of 50 nM. Table 16 below includes other antisense molecules tested at a concentration range of 5, 25, 50, 100, 200 and 300 nM. These antisense molecules showed a variable ability to induce exon

10 skipping

SEQ ID	Antisense Oligonucleotide name	Sequence	Ability to induce skipping
90	H21A(-06+16)	GCC GGU UGA CUU CAU CCU GUG C	Skips at 600 nM
91	H21A(+85+106)	CUG CAU CCA GGA ACA UGG GUC C	Skips at 50 nM
92	H21A(+85+108)	GUC UGC AUC CAG GAA CAU GGG UC	Skips at 50 nM
93	H21A(+08+31)	GUU GAA GAU CUG AUA GCC GGU UGA	Skips faintly to
94	H21D(+18-07)	UAC UUA CUG UCU GUA GCU CUU UCU	No skipping

Table 16

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 22

Antisense oligonucleotides directed at exon 22 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

15 described above.

Figure 12 illustrates differing efficiencies of two antisense molecules directed at exon 22 acceptor splice site. H22A(+125+106) [SEQ ID NO:96] and H22A(+80+101) [SEQ ID NO: 98] induce strong exon 22 skipping from 50 nM to 600 nM concentration.

5 H22A(+125+146) [SEQ ID NO:96] and H22A(+80+101) [SEQ ID NO:98] induced exon 22 skipping when delivered into cells at a concentration of 50 nM. Table 17 below shows other antisense molecules tested at a concentration range of 50, 100, 300 and 600 nM. These antisense molecules showed a variable ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
95	H22A(+22+45)	CAC UCA UGG UCU CCU GAU AGC GCA	No skipping
96	H22A(+125+146)	CUG CAA UUC CCC GAG UCU CUG C	Skipping to 50 nM
97	H22A(+47+69)	ACU GCU GGA CCC AUG UCC UGA UG	Skipping to 300 nM
98	H22A(+80+101)	CUA AGU UGA GGU AUG GAG AGU	Skipping to 50 nM
99	H22D(+13-11)	UAU UCA CAG ACC UGC AAU UCC CC	No skipping

10 Table 17

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 23

Antisense oligonucleotides directed at exon 23 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

15 Table 18 below shows antisense molecules tested at a concentration range of 25, 50, 100, 300 and 600 nM. These antisense molecules showed no ability to induce exon skipping or are yet to be tested.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
100	H23A(+34+59)	ACA GUG GUG CUG AGA UAG UAU AGG CC	No skipping
101	H23A(+18+39)	UAG GCC ACU UUG UUG CUC UUG C	No Skipping
102	H23A(+72+90)	UUC AGA GGG CGC UUU CUU C	No Skipping

Table 18

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 24

Antisense oligonucleotides directed at exon 24 were prepared using similar methods as described above. Table 19 below outlines the antisense oligonucleotides 5 directed at exon 24 that are yet to be tested for their ability to induce exon 24 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
103	H24A(+48+70)	GGG CAG GCC AUU CCU CCU UCA GA	Needs testing
104	H24A(-02+22)	UCU UCA GGG UUU GUA UGU GAU UCU	Needs testing

Table 19

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 25

Antisense oligonucleotides directed at exon 25 were prepared using similar 10 methods as described above. Table 20 below shows the antisense oligonucleotides directed at exon 25 that are yet to be tested for their ability to induce exon 25 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
105	H25A(+9+36)	CUG GGC UGA AUU GUC UGA AUA UCA CUG	Needs testing
106	H25A(+131+156)	CUG UUG GCA CAU GUG AUC CCA CUG AG	Needs testing
107	H25D(+16-08)	GUC UAU ACC UGU UGG CAC AUG UGA	Needs testing

Table 20

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 26

Antisense oligonucleotides directed at exon 26 were prepared using similar methods as described above. Table 21 below outlines the antisense oligonucleotides directed at exon 26 that are yet to be tested for their ability to induce exon 26 skipping.

5

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
108	H26A(+132+156)	UGC UUU CUG UAA UUC AUC UGG AGU U	Needs testing
109	H26A(-07+19)	CCU CCU UUC UGG CAU AGA CCU UCC AC	Needs testing
110	H26A(+68+92)	UGU GUC AUC CAU UCG UGC AUC UCU G	Faint skipping at 600 nM

Table 21

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 27

Antisense oligonucleotides directed at exon 27 were prepared using similar methods as described above. Table 22 below outlines the antisense oligonucleotides directed at exon 27 that are yet to be tested for their ability to induce exon 27 skipping.

10

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
111	H27A(+82+106)	UUA AGG CCU CUU GUG CUA CAG GUG G	Needs testing
112	H27A(-4+19)	GGG CCU CUU CUU UAG CUC UCU GA	Faint skipping at 600 and 300 nM
113	H27D(+19-03)	GAC UUC CAA AGU CUU GCA UUU C	v. strong skipping at 600 and 300 nM

Table 22

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 28

Antisense oligonucleotides directed at exon 28 were prepared using similar methods as described above. Table 23 below outlines the antisense oligonucleotides directed at exon 28 that are yet to be tested for their ability to induce exon 28 skipping.

15

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
114	H28A(-05+19)	GCC AAC AUG CCC AAA CUU CCU AAG	v. strong skipping at 600 and 300 nM
115	H28A(+99+124)	CAG AGA UUU CCU CAG CUC CGC CAG GA	Needs testing
116	H28D(+16-05)	CUU ACA UCU AGC ACC UCA GAG	v. strong skipping at 600 and 300 nM

Table 23

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 29

Antisense oligonucleotides directed at exon 29 were prepared using similar methods as described above. Table 24 below outlines the antisense oligonucleotides directed at exon 29 that are yet to be tested for their ability to induce exon 29 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
117	H29A(+57+81)	UCC GCC AUC UGU UAG GGU CUG UGC C	Needs testing
118	H29A(+18+42)	AUU UGG GUU AUC CUC UGA AUG UCG C	v. strong skipping at 600 and 300 nM
119	H29D(+17-05)	CAU ACC UCU UCA UGU AGU UCC C	v. strong skipping at 600 and 300 nM

Table 24

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 30

Antisense oligonucleotides directed at exon 30 were prepared using similar methods as described above. Table 25 below outlines the antisense oligonucleotides directed at exon 30 that are yet to be tested for their ability to induce exon 30 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
120	H30A(+122+147)	CAU UUG AGC UGC GUC CAC CUU GUC UG	Needs testing
121	H30A(+25+50)	UCC UGG GCA GAC UGG AUG CUC UGU UC	Very strong skipping at 600 and 300 nM.
122	H30D(+19-04)	UUG CCU GGG CUU CCU GAG GCA UU	Very strong skipping at 600 and 300 nM.

Table 25

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 31

Antisense oligonucleotides directed at exon 31 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as

5 described above.

Figure 13 illustrates differing efficiencies of two antisense molecules directed at exon 31 acceptor splice site and a "cocktail" of exon 31 antisense oligonucleotides at varying concentrations. H31D(+03-22) [SEQ ID NO:124] substantially induced exon 31 skipping when delivered into cells at a concentration of 20 nM. Table 26 below also includes other antisense molecules tested at a concentration of 100 and 300 nM. These antisense molecules showed a variable ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
123	H31D(+06-18)	UUC UGA AAU AAC AUA UAC CUG UGC	Skipping to 300 nM
124	H31D(+03-22)	UAG UUU CUG AAA UAA CAU AUA CCU G	Skipping to 20 nM
125	H31A(+05+25)	GAC UUG UCA AAU CAG AUU GGA	No skipping
126	H31D(+04-20)	GUU UCU GAA AUA ACA UAU ACC UGU	Skipping to 300 nM

Table 26

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 32

Antisense oligonucleotides directed at exon 32 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

5 H32D(+04-16) [SEQ ID NO:127] and H32A(+49+73) [SEQ ID NO:130] induced exon 32 skipping when delivered into cells at a concentration of 300 nM. Table 27 below also shows other antisense molecules tested at a concentration of 100 and 300 nM. These antisense molecules did not show an ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
127	H32D(+04-16)	CAC CAG AAA UAC AUA CCA CA	Skipping to 300 nM
128	H32A(+151+170)	CAA UGA UUU AGC UGU GAC UG	No skipping
129	H32A(+10+32)	CGA AAC UUC AUG GAG ACA UCU UG	No skipping
130	H32A(+49+73)	CUU GUA GAC GCU GCU CAA AAU UGG C	Skipping to 300 nM

10 Table 27

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 33

Antisense oligonucleotides directed at exon 33 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

15 Figure 14 shows differing efficiencies of two antisense molecules directed at exon 33 acceptor splice site. H33A(+64+88) [SEQ ID NO:134] substantially induced exon 33 skipping when delivered into cells at a concentration of 10 nM. Table 28 below includes other antisense molecules tested at a concentration of 100, 200 and 300 nM. These antisense molecules showed a variable ability to induce exon skipping.

20

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
131	H33D(+09-11)	CAU GCA CAC ACC UUU GCU CC	No skipping
132	H33A(+53+76)	UCU GUA CAA UCU GAC GUC CAG UCU	Skipping to 200 nM
133	H33A(+30+56)	GUG UUU AUC ACC AUU UCC ACU UCA GAC	Skipping to 200 nM
134	H33A(+64+88)	GCG UCU GCU UUU UCU GUA CAA UCU G	Skipping to 10 nM

Table 28

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 34

Antisense oligonucleotides directed at exon 34 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as 5 described above.

Table 29 below includes antisense molecules tested at a concentration of 100 and 300 nM. These antisense molecules showed a variable ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
135	H34A(+83+104)	UCC AUA UCU GUA GCU GGC AGC C	No skipping
136	H34A(+143+165)	CCA GGC AAC UUC AGA AUC CAA AU	No skipping
137	H34A(-20+10)	UUU CUG UUA CCU GAA AAG AAU UAU AAU GAA	Not tested
138	H34A(+46+70)	CAU UCA UUU CCU UUC GCA UCU UAC G	Skipping to 300 nM
139	H34A(+95+120)	UGA UCU CUU UGU CAA UUC CAU AUC UG	Skipping to 300 nM
140	H34D(+10-20)	UUC AGU GAU AUA GGU UUU ACC UUU CCC CAG	Not tested
141	H34A(+72+96)	CUG UAG CUG CCA GCC AUU CUG UCA AG	No skipping

Table 29

10

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 35

Antisense oligonucleotides directed at exon 35 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

5 Figure 15 shows differing efficiencies of antisense molecules directed at exon 35 acceptor splice site. H35A(+24+43) [SEQ ID NO:144] substantially induced exon 35 skipping when delivered into cells at a concentration of 20 nM. Table 30 below also includes other antisense molecules tested at a concentration of 100 and 300 nM. These antisense molecules showed no ability to induce exon skipping.

10

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
142	H35A(+141+161)	UCU UCU GCU CGG GAG GUG ACA	Skipping to 20 nM
143	H35A(+116+135)	CCA GUU ACU AUU CAG AAG AC	No skipping
144	H35A(+24+43)	UCU UCA GGU GCA CCU UCU GU	No skipping

Table 30

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 36

Antisense oligonucleotides directed at exon 36 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

15

Antisense molecule H36A(+26+50) [SEQ ID NO:145] induced exon 36 skipping when delivered into cells at a concentration of 300 nM, as shown in Figure 16.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 37

Antisense oligonucleotides directed at exon 37 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

20

Figure 17 shows differing efficiencies of two antisense molecules directed at exon 37 acceptor splice site. H37A(+82+105) [SEQ ID NO:148] and H37A(+134+157)

[SEQ ID NO:149] substantially induced exon 37 skipping when delivered into cells at a concentration of 10 nM. Table 31 below shows the antisense molecules tested.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
147	H37A(+26+50)	CGU GUA GAG UCC ACC UUU GGG CGU A	No skipping
148	H37A(+82+105)	UAC UAA UUU CCU GCA GUG GUC ACC	Skipping to 10 nM
149	H37A(+134+157)	UUC UGU GUG AAA UGG CUG CAA AUC	Skipping to 10 nM

Table 31

5 ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 38

Antisense oligonucleotides directed at exon 38 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 18 illustrates antisense molecule H38A(+88+112) [SEQ ID NO:152] , directed at exon 38 acceptor splice site. H38A(+88+112) substantially induced exon 38 skipping when delivered into cells at a concentration of 10 nM. Table 32 below shows the antisense molecules tested and their ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
150	H38A(-01+19)	CCU UCA AAG GAA UGG AGG CC	No skipping
151	H38A(+59+83)	UGC UGA AUU UCA GCC UCC AGU GGU U	Skipping to 10 nM
152	H38A(+88+112)	UGA AGU CUU CCU CUU UCA GAU UCA C	Skipping to 10 nM

Table 32

15 ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 39

Antisense oligonucleotides directed at exon 39 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

H39A(+62+85) [SEQ ID NO:153] induced exon 39 skipping when delivered into cells at a concentration of 100 nM. Table 33 below shows the antisense molecules tested and their ability to induce exon skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
153	H39A(+62+85)	CUG GCU UUC UCU CAU CUG UGA UUC	Skipping to 100 nM
154	H39A(+39+58)	GUU GUA AGU UGU CUC CUC UU	No skipping
155	H39A(+102+121)	UUG UCU GUA ACA GCU GCU GU	No skipping
156	H39D(+10-10)	GCU CUA AUA CCU UGA GAG CA	Skipping to 300 nM

5

Table 33

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 40

Antisense oligonucleotides directed at exon 40 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

10 Figure 19 illustrates antisense molecule H40A(-05+17) [SEQ ID NO:157] directed at exon 40 acceptor splice site. H40A(-05+17) and H40A(+129+153) [SEQ ID NO:158] both substantially induced exon 40 skipping when delivered into cells at a concentration of 5 nM.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 42

15 Antisense oligonucleotides directed at exon 42 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 20 illustrates antisense molecule H42A(-04+23) [SEQ ID NO:159], directed at exon 42 acceptor splice site. H42A(-4+23) and H42D(+19-02) [SEQ ID NO:161] both induced exon 42 skipping when delivered into cells at a concentration of 5 nM. Table 34 below shows the antisense molecules tested and their ability to induce exon 42 skipping.

SEQ ID	Antisense afigonucleotide name	Sequence	Ability to induce skipping
159	H42A(-4+23)	AUC GUU UCU UCA CGG ACA GUG UGG UGC	Skipping to 5 nM
160	H42A(+86+109)	GGG CUU GUG AGA CAU GAG UGA UUU	Skipping to 100 nM
161	H42D(+19-02)	A CCU UCA GAG GAC UCC UCU UGC	Skipping to 5 nM

Table 34

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 43

Antisense oligonucleotides directed at exon 43 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as 5 described above.

H43A(+101+120) [SEQ ID NO:163] induced exon 43 skipping when delivered into cells at a concentration of 25 nM. Table 35 below includes the antisense molecules tested and their ability to induce exon 43 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
162	H43D(+10-15)	UAU GUG UUA CCU ACC CUU GUC GGU C	Skipping to 100 nM
163	H43A(+101+120)	GGA GAG AGC UUC CUG UAG CU	Skipping to 25 nM
164	H43A(+78+100)	UCA CCC UUU CCA CAG GCG UUG CA	Skipping to 200 n M

10

Table 35

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 44

Antisense oligonucleotides directed at exon 44 were prepared using similar methods as described above. Testing ffor the ability of these antisense molecules to induce exon 44 skipping is still in progress. The antisense molecules under review are shown as 15 SEQ ID Nos: 165 to 167 in Table 1A.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 45

Antisense oligonucleotides directed at exon 45 were prepared using similar methods as described above. Testing for the ability of these antisense molecules to induce exon 45 skipping is still in progress. The antisense molecules under review are shown as

5 SEQ ID Nos: 207 to 211 in Table 1A.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 46

Antisense oligonucleotides directed at exon 46 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

10 Figure 21 illustrates the efficiency of one antisense molecule directed at exon 46 acceptor splice site. Antisense oligonucleotide H46A(+86+115) [SEQ ID NO:203] showed very strong ability to induce exon 46 skipping. Table 36 below includes antisense molecules tested. These antisense molecules showed varying ability to induce exon 46 skipping.

15

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
168	H46D(+16-04)	UUA CCU UGA CUU GCU CAA GC	No skipping
169	H46A(+90+109)	UCC AGG UUC AAG UGG GAU AC	No skipping
203	H46A(+86+115)	CUC UUU UCC AGG UUC AAG UGG GAU ACU AGC	Good skipping to 100 nM
204	H46A(+107+137)	CAA GCU UUU CUU UUA GUU GCU GCU CUU UUC C	Good skipping to 100 nM
205	H46A(-10+20)	UAU UCU UUU GUU CUU CUA GCC UGG AGA AAG	Weak skipping
206	H46A(+50+77)	CUG CUU CCU CCA ACC AUA AAA CAA AUU C	Weak skipping

Table 36

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 47

Antisense oligonucleotides directed at exon 47 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

5 H47A(+76+100) [SEQ ID NO:170] and H47A(-09+12) [SEQ ID NO:172] both induced exon 47 skipping when delivered into cells at a concentration of 200 nM. H47D(+25-02) [SEQ ID NO: 171] is yet to be prepared and tested.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 50

10 Antisense oligonucleotides directed at exon 50 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Antisense oligonucleotide molecule H50A(+02+30) [SEQ ID NO: 173] was a strong inducer of exon skipping. Further, H50A(+07+33) [SEQ ID NO:174] and H50D(+07-18) [SEQ ID NO:175] both induced exon 50 skipping when delivered into cells
15 at a concentration of 100 nM.

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 51

Antisense oligonucleotides directed at exon 51 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

20 Figure 22 illustrates differing efficiencies of two antisense molecules directed at exon 51 acceptor splice site. Antisense oligonucleotide H51A(+66+90) [SEQ ID NO:180] showed the stronger ability to induce exon 51 skipping. Table 37 below includes antisense molecules tested at a concentration range of 25, 50, 100, 300 and 600 nM. These antisense molecules showed varying ability to induce exon 51 skipping. The
25 strongest inducers of exon skipping were antisense oligonucleotide H51A(+61+90) [SEQ ID NO: 179] and H51A(+66+95) [SEQ ID NO: 181].

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
176	H51A(-01+25)	ACC AGA GUA ACA GUC UGA GUA GGA GC	Faint skipping
177	H51D(+16-07)	CUC AUA CCU UCU GCU UGA UGA UC	Skipping at 300 nM
178	H51A(+111+134)	UUC UGU CCA AGC CCG GUU GAA AUC	Needs re- testing
179	H51A(+61+90)	ACA UCA AGG AAG AUG GCA UUU CUA GUU UGG	Very strong skipping
180	H51A(+66+90)	ACA UCA AGG AAG AUG GCA UUU CUA G	skipping
181	H51A(+66+95)	CUC CAA CAU CAA GGA AGA UGG CAU UUC UAG	Very strong skipping
182	H51D(+08-17)	AUC AUU UUU UCU CAU ACC UUC UGC U	No skipping
183	H51A/D(+08-17) & (-15+?)	AUC AUU UUU UCU CAU ACC UUC UGC UAG GAG CUA AAA	No skipping
184	H51A(+175+195)	CAC CCA CCA UCA GCC UCU GUG	No skipping
185	H51A(+199+220)	AUC AUC UCG UUG AUA UCC UCA A	No skipping

Table 37

ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 52

Antisense oligonucleotides directed at exon 52 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 22 also shows differing efficiencies of four antisense molecules directed at exon 52 acceptor splice site. The most effective antisense oligonucleotide for inducing exon 52 skipping was H52A(+17+37) [SEQ ID NO:188).

Table 38 below shows antisense molecules tested at a concentration range of 50, 100, 300 and 600 nM. These antisense molecules showed varying ability to induce exon 50 skipping. Antisense molecules H52A(+12+41) [SEQ ID NO:187] and

H52A(+17+37) [SEQ ID NO:188] showed the strongest exon 50 skipping at a concentration of 50 nM.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
186	H52A(-07+14)	UCC UGC AUU GUU GCC UGU AAG	No skipping
187	H52A(+12+41)	UCC AAC UGG GGA CGC CUC UGU UCC AAA UCC	Very strong skipping
188	H52A(+17+37)	ACU GGG GAC GCC UCU GUU CCA	Skipping to 50 nM
189	H52A(+93+112)	CCG UAA UGA UUG UUC UAG CC	No skipping
190	H52D(+05-15)	UGU UAA AAA ACU UAC UUC GA	No skipping

Table 38

5 ANTISENSE OLIGONUCLEOTIDES DIRECTED AT EXON 53

Antisense oligonucleotides directed at exon 53 were prepared and tested for their ability to induce exon skipping in human muscle cells using similar methods as described above.

Figure 22 also shows antisense molecule H53A(+39+69) [SEQ ID NO:193] directed at exon 53 acceptor splice site. This antisense oligonucleotide was able to induce exon 53 skipping at 5, 100, 300 and 600 nM. A "cocktail" of three exon 53 antisense oligonucleotides: H53A(+23+47) [SEQ ID NO:195], H53A(+150+176) [SEQ ID NO:196] and H53D(+14-07) [SEQ ID NO:194], was also tested, as shown in Figure 20 and exhibited an ability to induce exon skipping.

Table 39 below includes other antisense molecules tested at a concentration range of 50, 100, 300 and 600 nM. These antisense molecules showed varying ability to induce exon 53 skipping. Antisense molecule H53A(+39+69) [SEQ ID NO:193] induced the strongest exon 53 skipping.

SEQ ID	Antisense oligonucleotide name	Sequence	Ability to induce skipping
191	H53A(+45+69)	CAU UCA ACU GUU GCC UCC GGU UCU G	Faint skipping at 50 nM
192	H53A(+39+62)	CUG UUG CCU CCG GUU CUG AAG GUG	Faint skipping at 50 nM
193	H53A(+39+69)	CAU UCA ACU GUU GCC UCC GGU UCU GAA GGU G	Strong skipping to 50 nM
194	H53D(+14-07)	UAC UAA CCU UGG UUU CUG UGA	Very faint skipping to 50 nM
195	H53A(+23+47)	CUG AAG GUG UUC UUG UAC UUC AUC C	Very faint skipping to 50 nM
196	H53A(+150+176)	UGU AUA GGG ACC CUC CUU CCA UGA CUC	Very faint skipping to 50 nM
197	H53D(+20-05)	CUA ACC UUG GUU UCU GUG AUU UUC U	Not made yet
198	H53D(+09-18)	GGU AUC UUU GAU ACU AAC CUU GGU UUC	Faint at 600 nM
199	H53A(-12+10)	AUU CUU UCA ACU AGA AUA AAA G	No skipping
200	H53A(-07+18)	GAU UCU GAA UUG UUU CAA CUA GAA U	No skipping
201	H53A(+07+26)	AUC CCA CUG AUU CUG AAU UC	No skipping
202	H53A(+124+145)	UUG GCU CUG GCC UGU CCU AAG A	No skipping

Table 39

What is claimed is:

1. An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.
2. A pharmaceutical composition comprising: (i) an antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping, or a pharmaceutically acceptable salt thereof; and (ii) a pharmaceutically acceptable carrier.

ABSTRACT

An antisense molecule capable of binding to a selected target site to induce
5 exon skipping in the dystrophin gene, as set forth in SEQ ID NO: 1 to 214.

10

FIGURE 1

bp Acceptor ESE Donor 1/22

ucaugcacugagugaccucuuucucgcagGCGCUAGCUGGAGCA/////CCGUGCAGACUGACGgucucau

SEQ ID NO:213 SEQ ID NO:214

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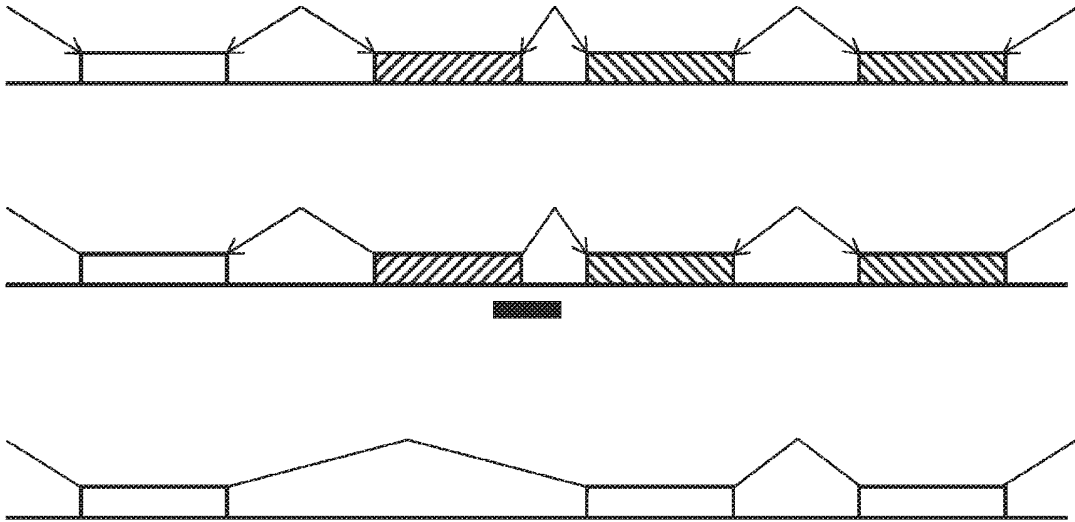


FIGURE 2

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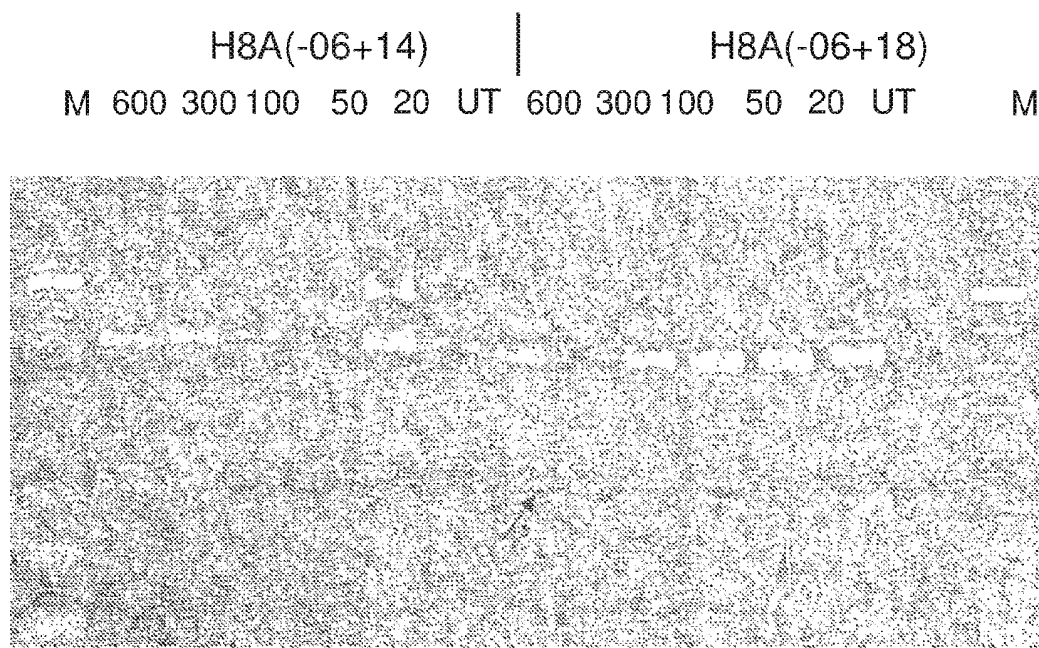


FIGURE 3

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H7A(+45+67) H7A(+2+26)
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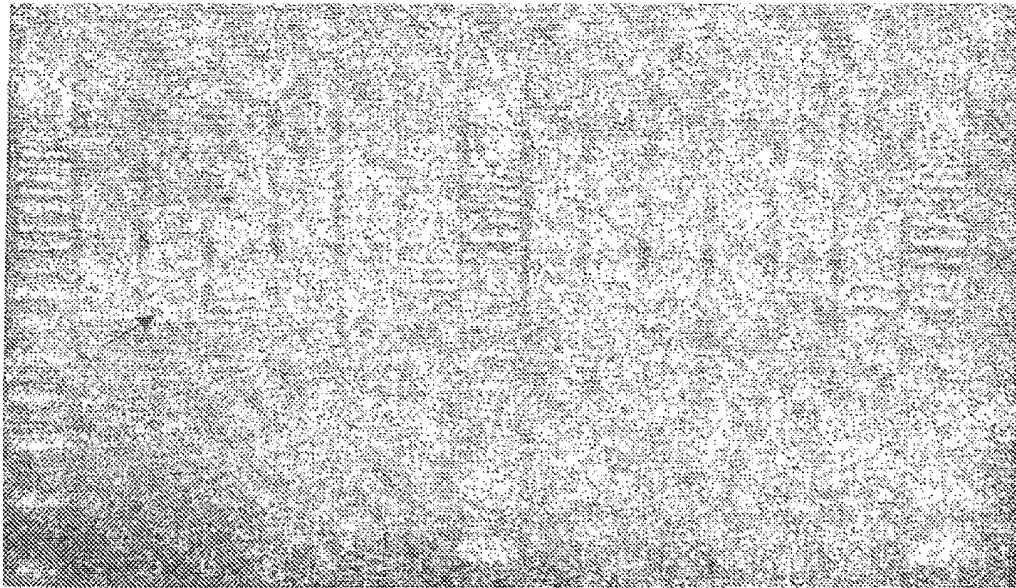


FIGURE 4

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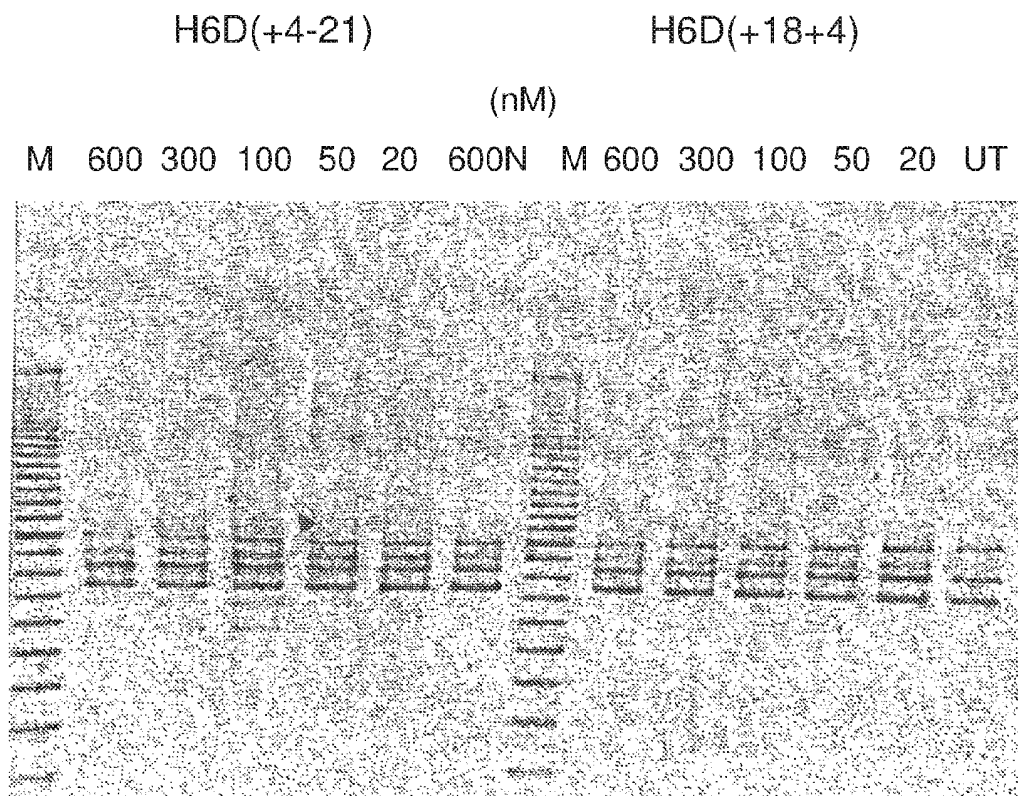


FIGURE 5

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6A(+69+91)

M 600 300 200 100 50 20 UT

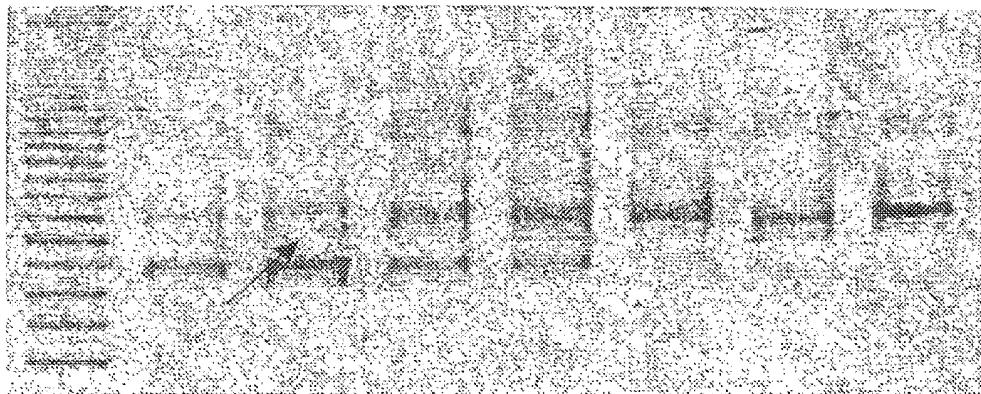


FIGURE 6

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H4A(+13+32)

M 600 300 100 50 20 UT Neg M

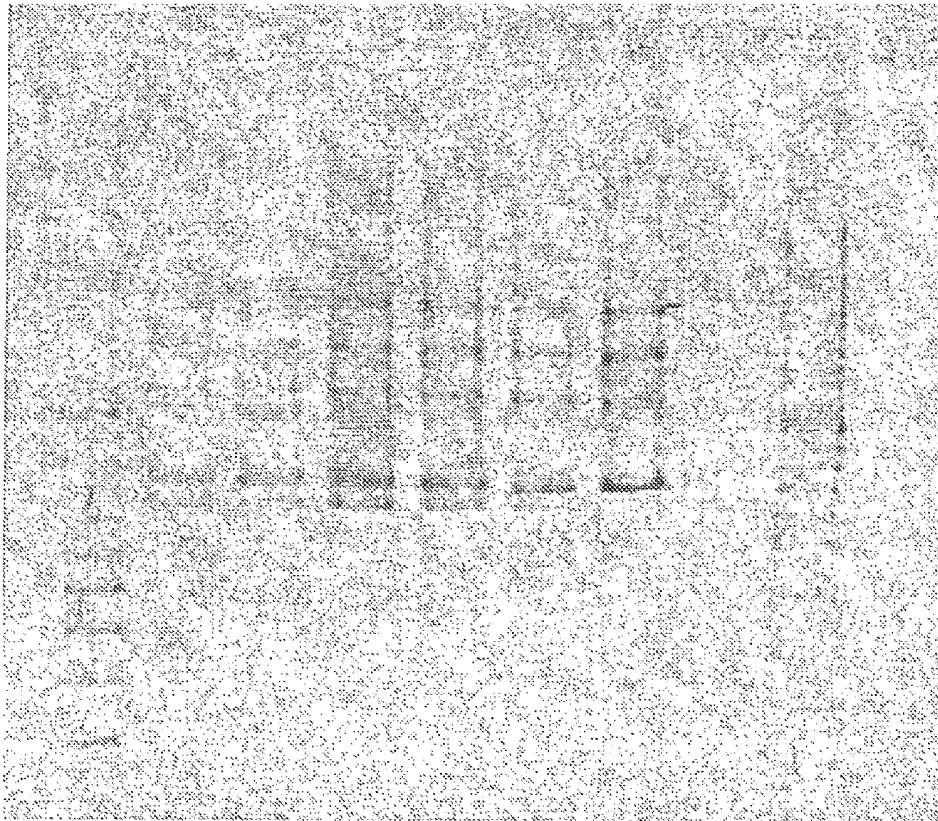


FIGURE 7

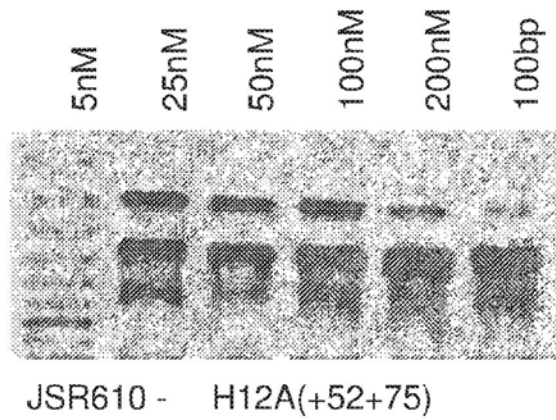


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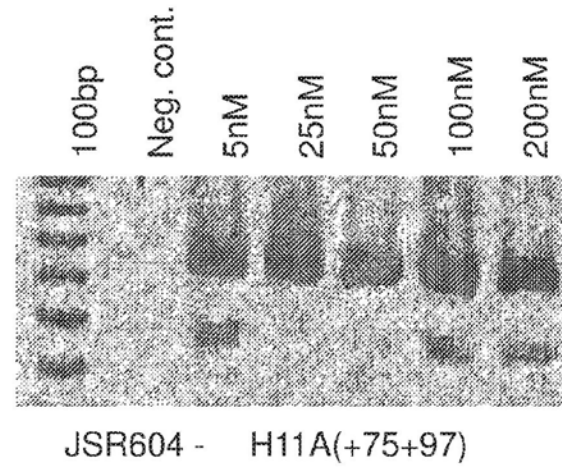


FIGURE 8B

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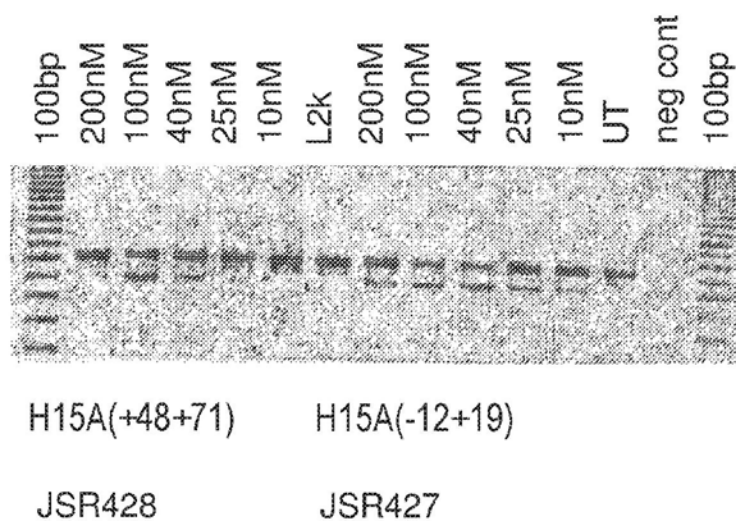


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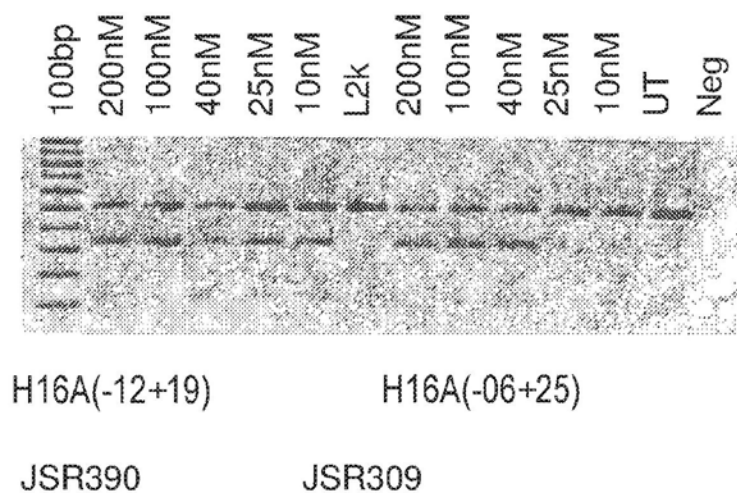


FIGURE 9B

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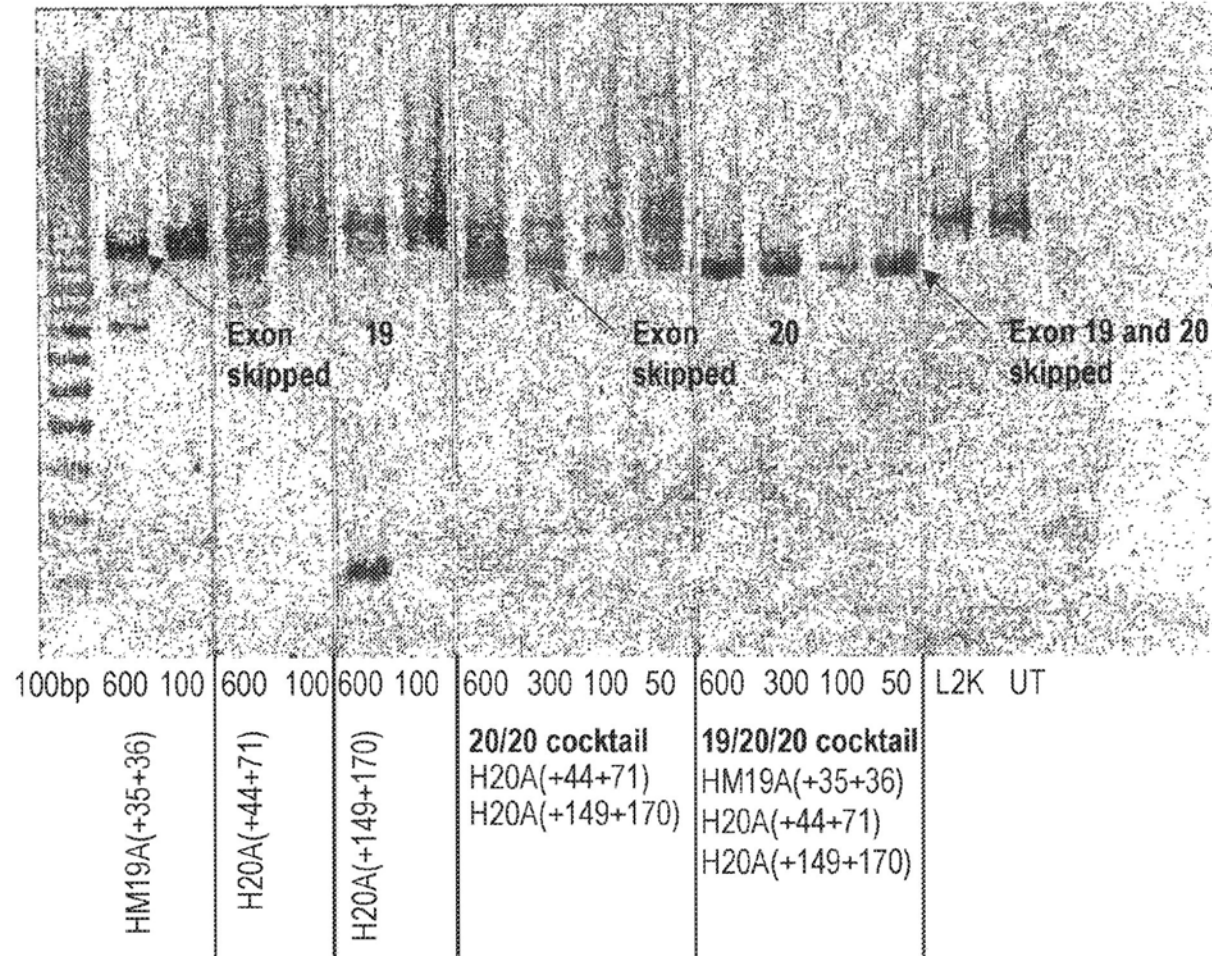
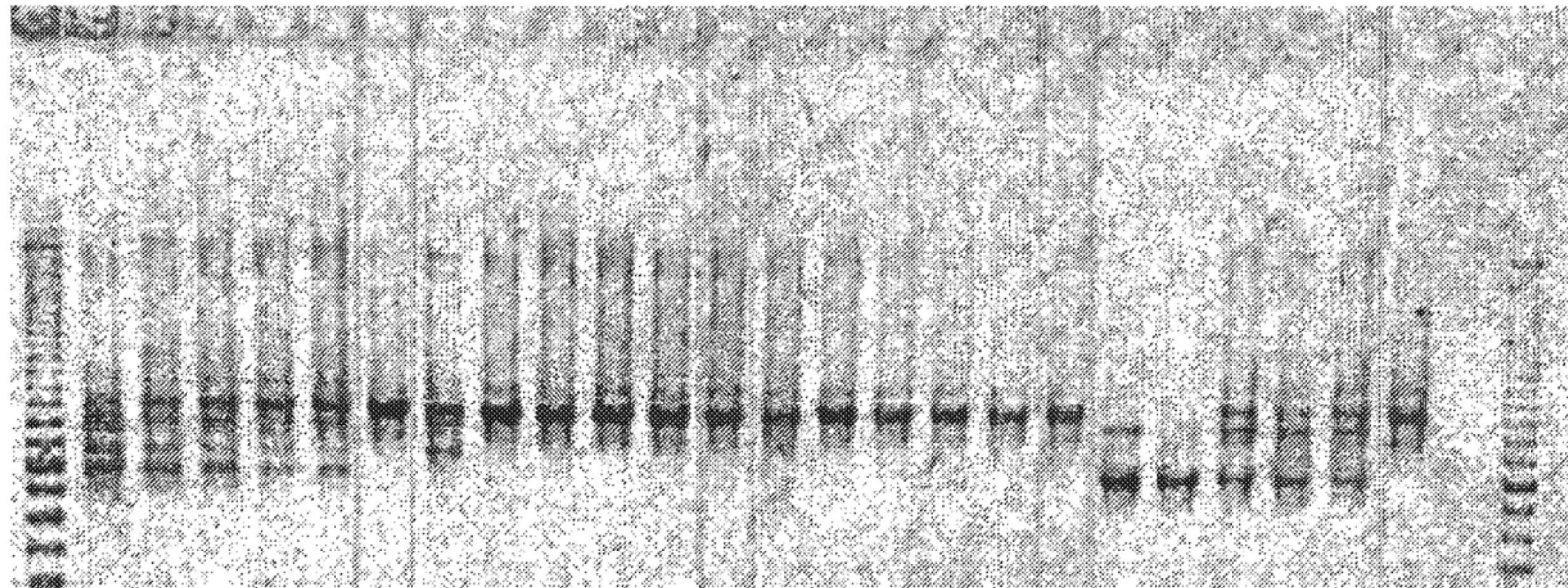


FIGURE 10

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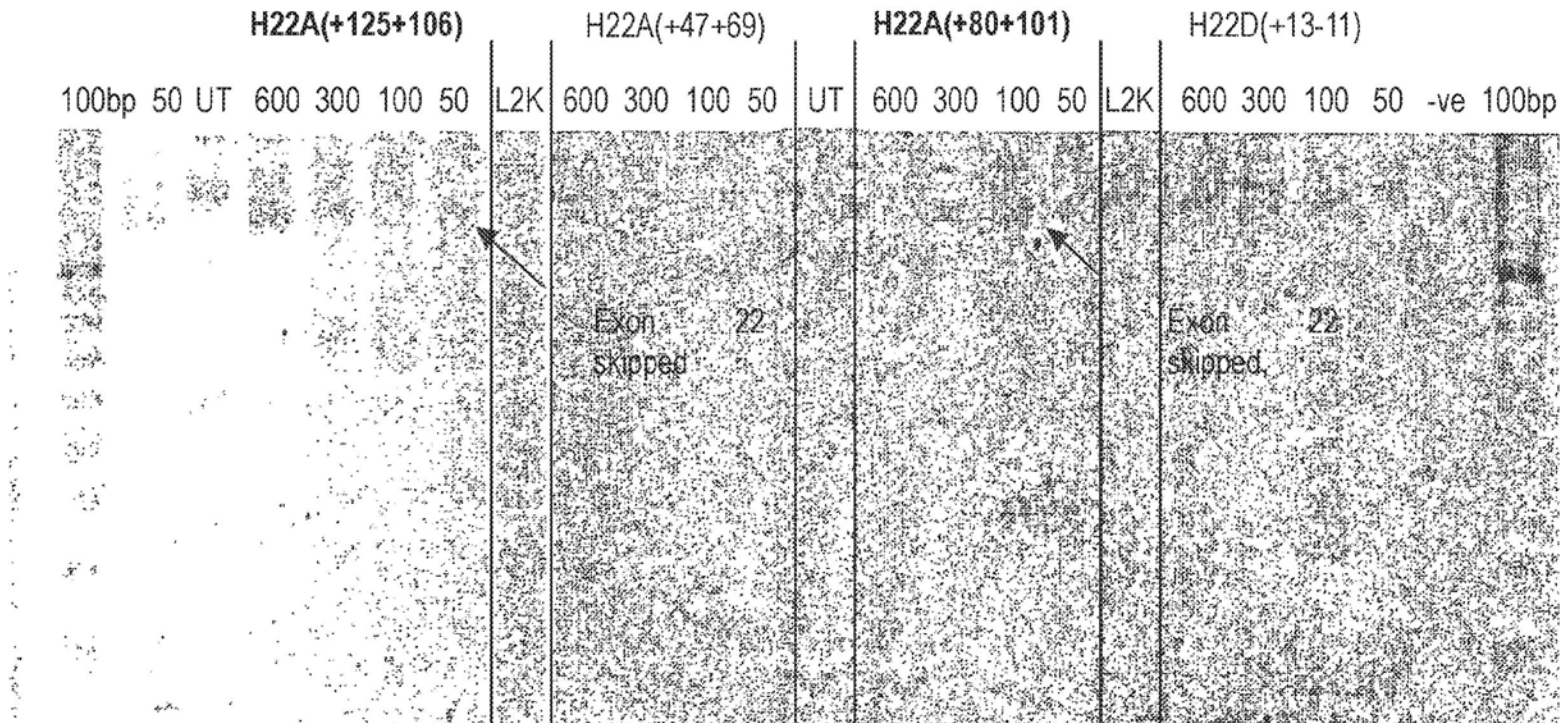
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H20A(+44+63)-aa-
H20A(+149+168)

Weasel19/20
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aa-
H20A(+44+63)

Weasel19/20
H19A(+35+53)-
aa-
H20A(+149+168)

19/20/20 cocktail
HM19A(+35+36)
H20A(+44+71)
H20A(+149+170)

FIGURE 11



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FIGURE 12

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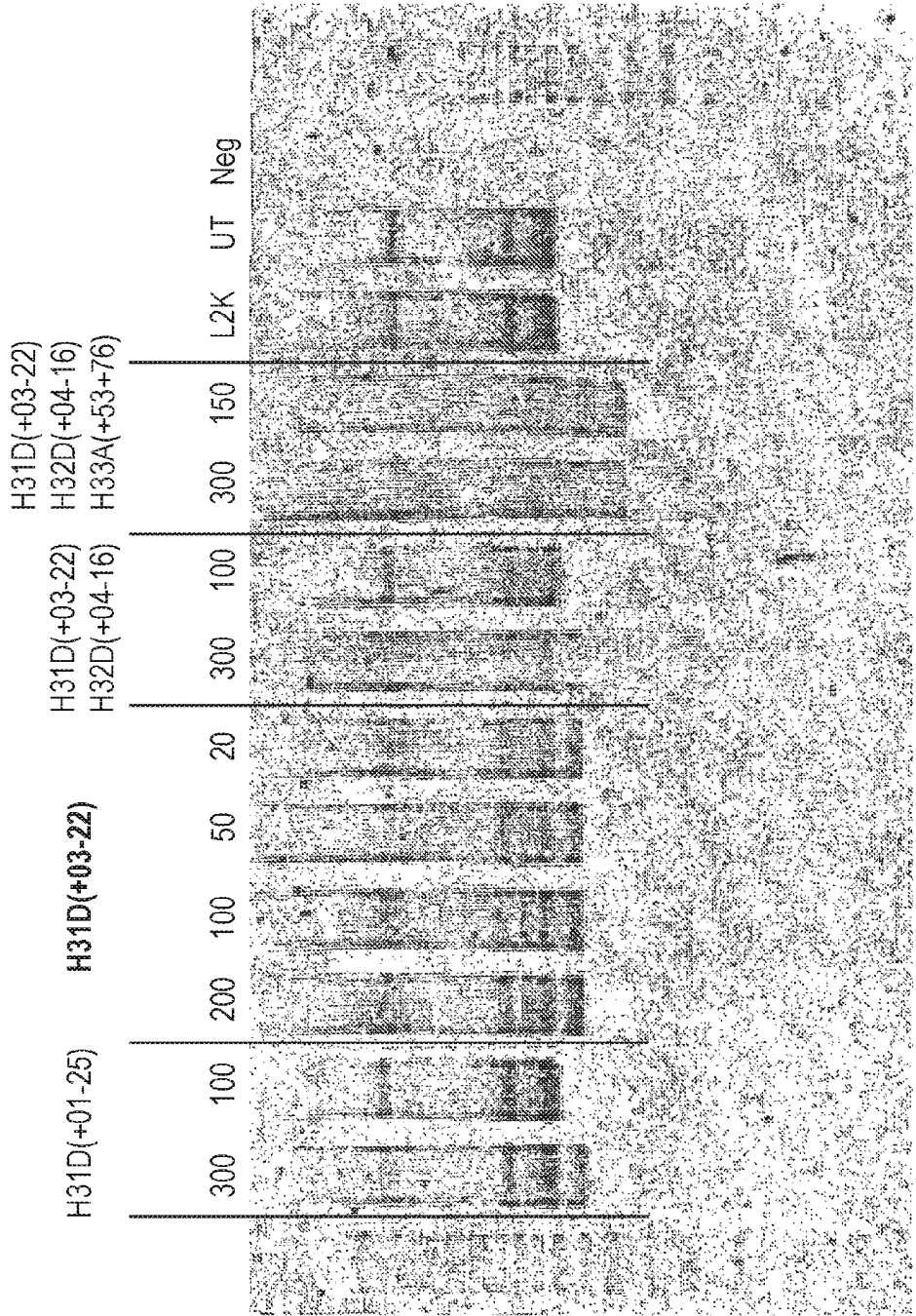


FIGURE 13

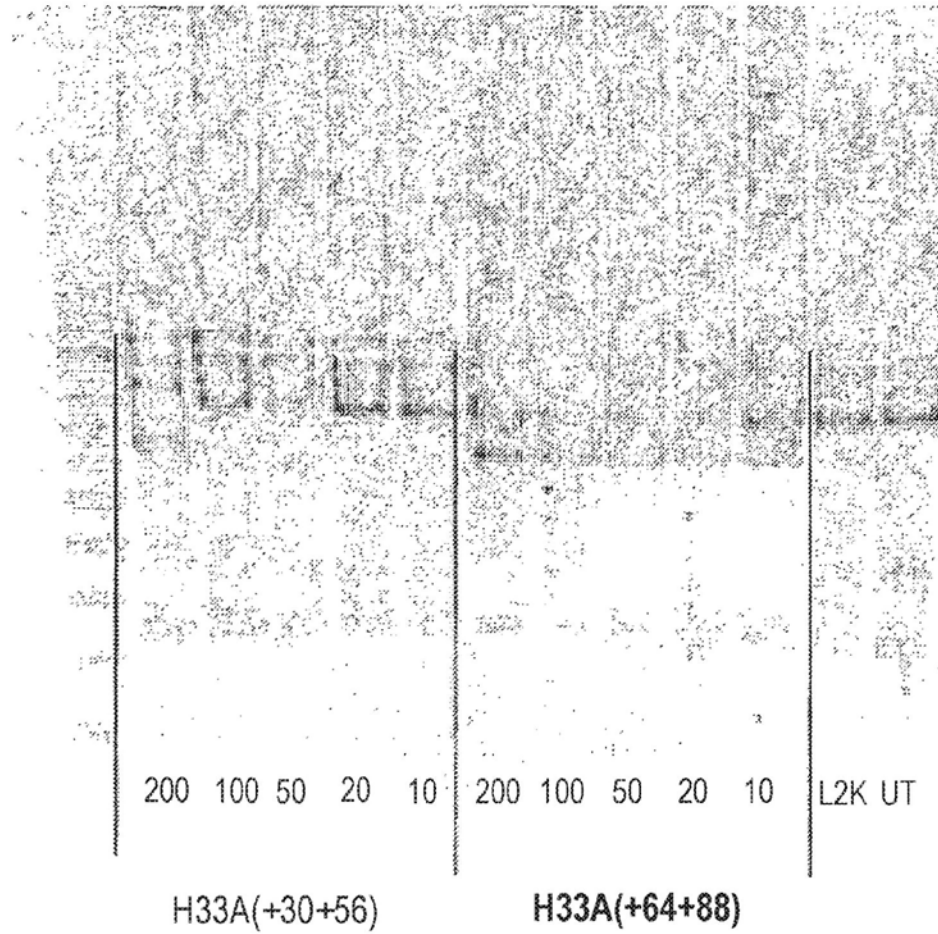


FIGURE 14

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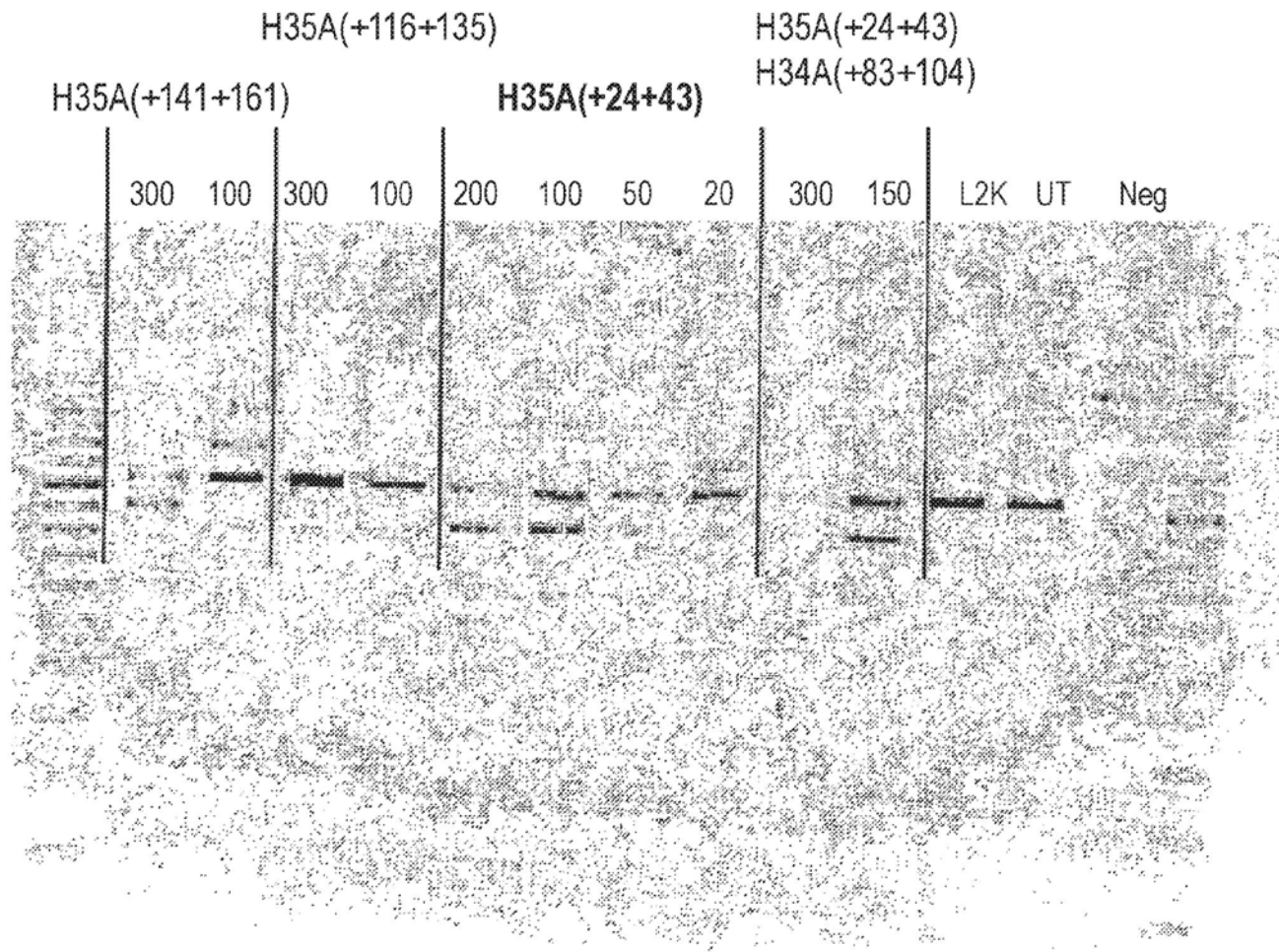


FIGURE 15

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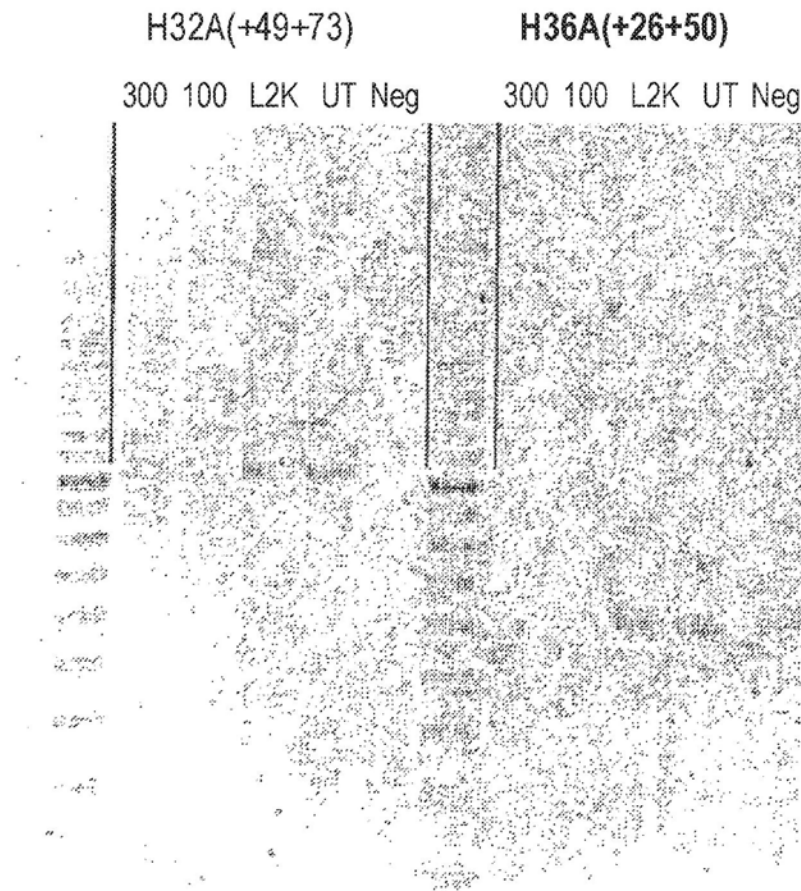


FIGURE 16

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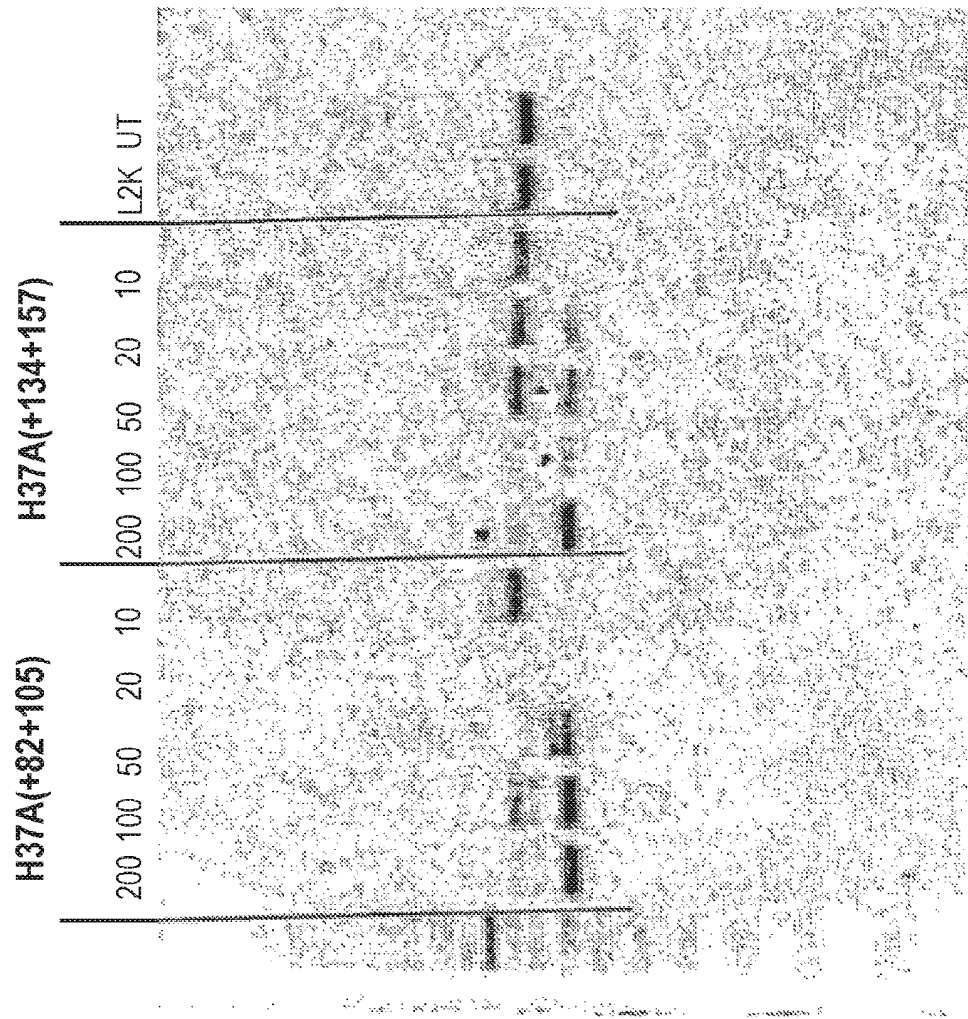


FIGURE 17

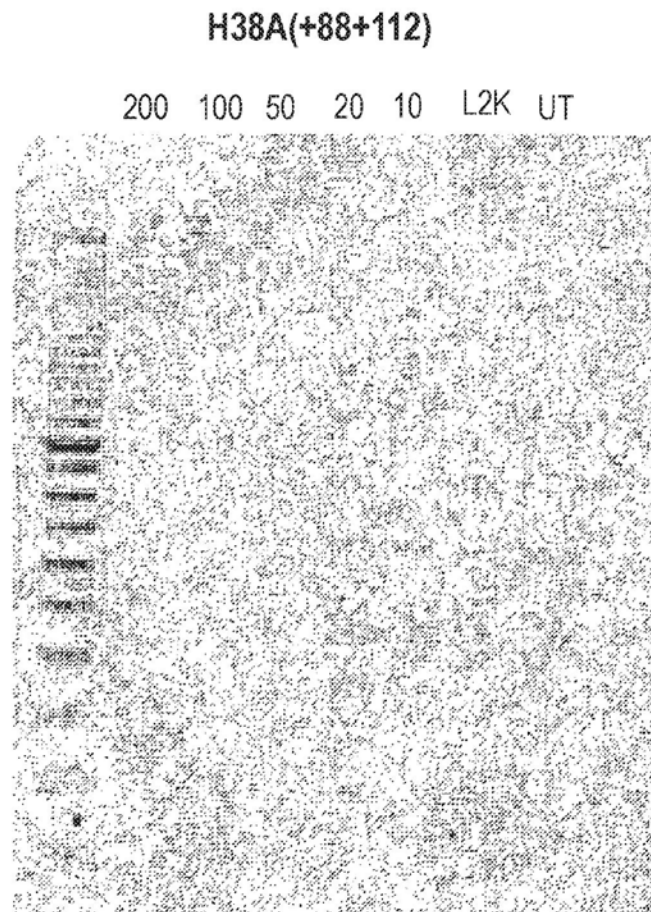


FIGURE 18

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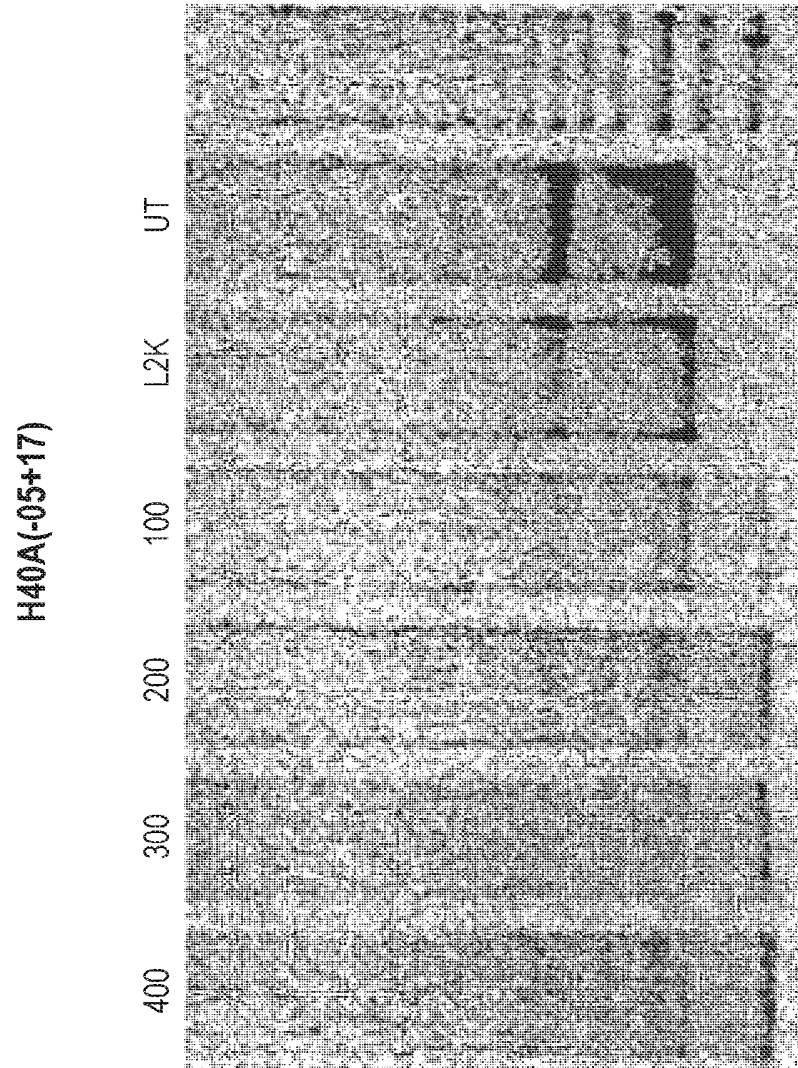


FIGURE 19

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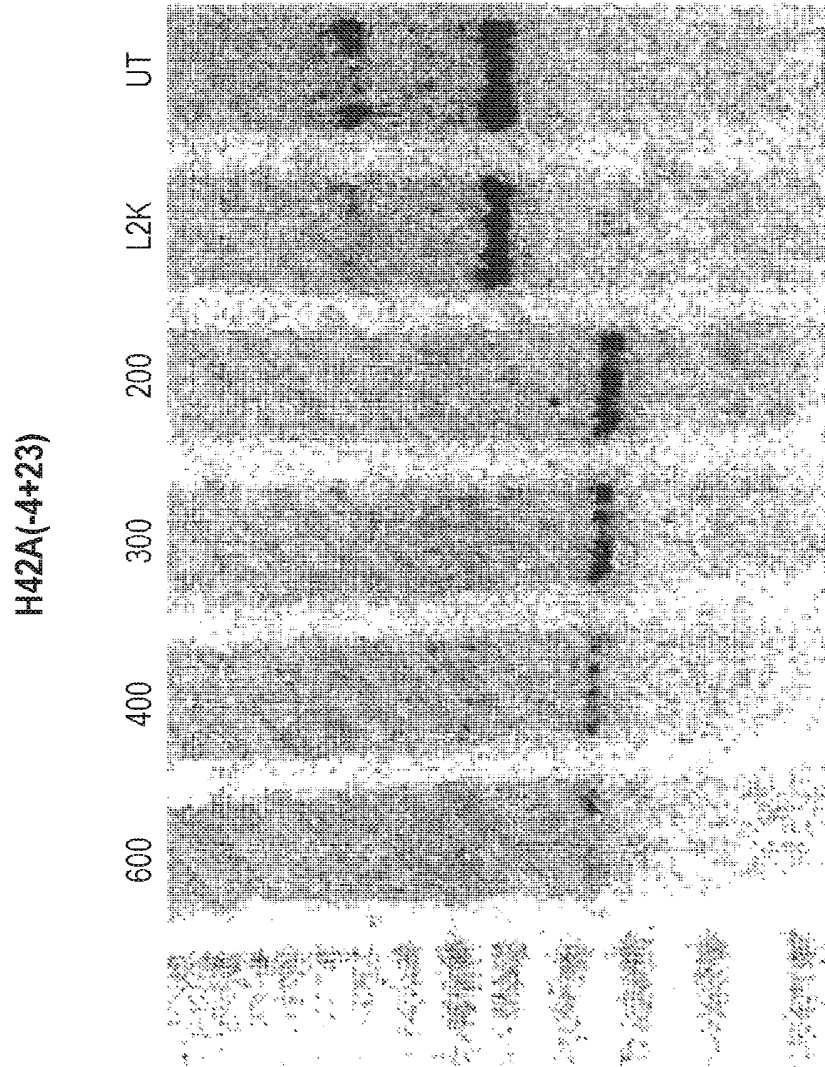
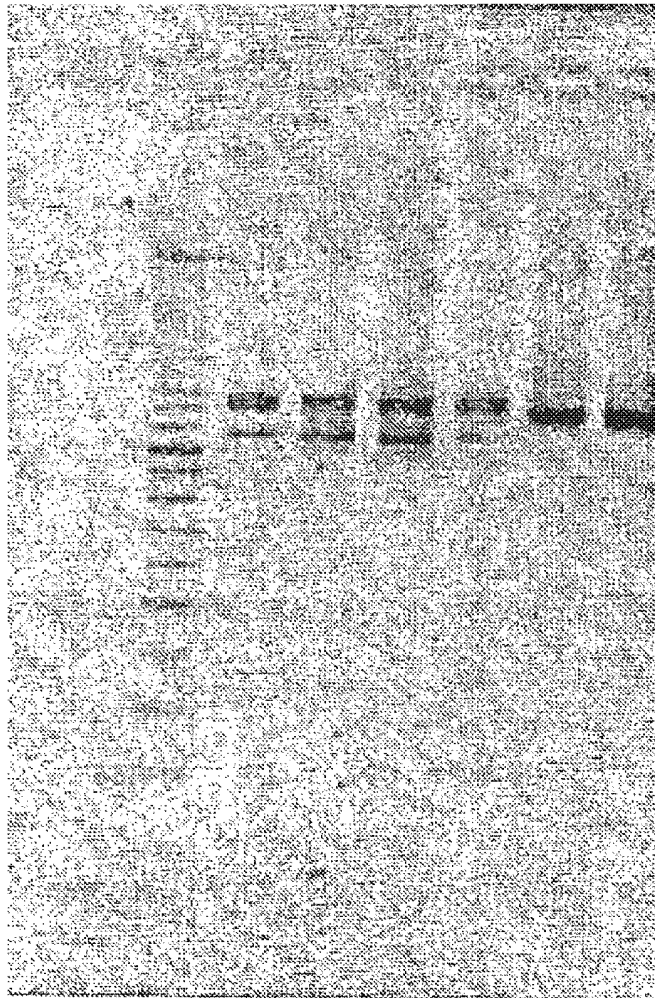


FIGURE 20

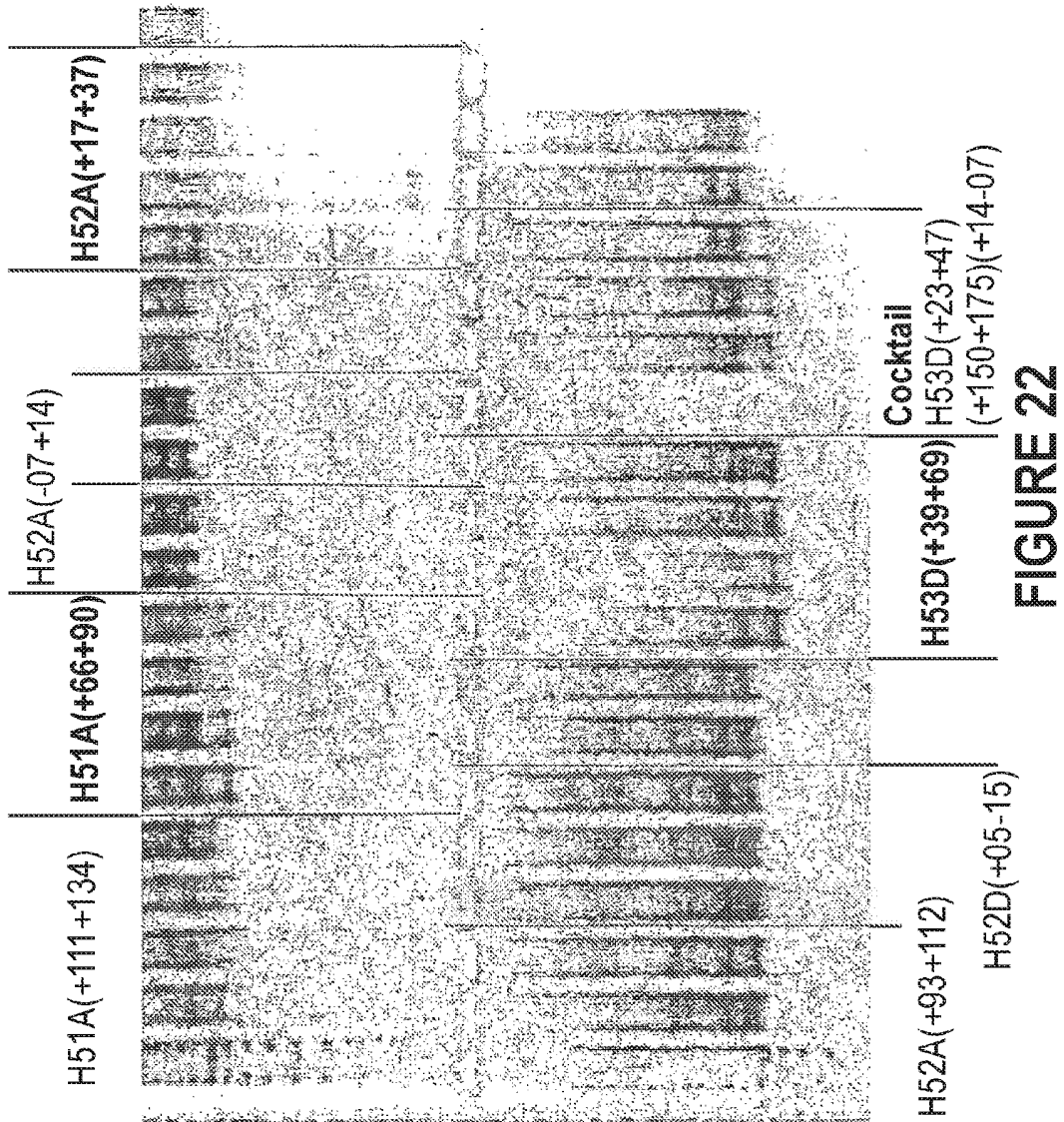
21/22

H46A(+86+115)

600 300 200 100 L2K UT

**FIGURE 21**

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Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
First Named Inventor/Applicant Name:		Stephen Donald WILTON		
Filer:		John Michael Covert/Tamara Haynesworth		
Attorney Docket Number:		4140.01500B0		
Filed as Small Entity				
Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

33187

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2855

Electronic Acknowledgement Receipt

EFS ID:	33536204
Application Number:	16112371
International Application Number:	
Confirmation Number:	5407
Title of Invention:	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Stephen Donald WILTON
Customer Number:	153767
Filer:	John Michael Covert/Tamara Haynesworth
Filer Authorized By:	John Michael Covert
Attorney Docket Number:	4140.01500B0
Receipt Date:	24-AUG-2018
Filing Date:	
Time Stamp:	17:59:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$2855
RAM confirmation Number	082718INTEFSW18021900
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			e10e90a7ea5ea1304a6c08b4d0be13f61dbba467		
Warnings:					
Information:					
2	Transmittal of New Application	2018-08-24-Utility-Transmittal-4140-01500B0.PDF	212934	no	2
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3	TrackOne Request	2018-08-24-Request-TrackOne-4140-01500B0.PDF	500691	no	1
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4	Authorization for Extension of Time all replies	2018-08-24-EOT-Authorization-4140-01500B0.PDF	116478	no	1
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5	Application Data Sheet	2018-08-24-ADS-4140-01500B0.PDF	489824	no	9
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Case 1:21-cv-01015-JLH Document 435-2 Filed 12/18/23 Page 110 of 399 PageID #: 33190

Multipart Description/PDF files in .zip description					
	Document Description		Start	End	
	Specification		1	66	
	Claims		67	67	
	Abstract		68	68	
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7	Drawings-other than black and white line drawings	2018-08-24-Drawings-4140-01500B0.PDF	3059628 fd8a2e7426aa09421ac2e557b9dd68b4406566d0	no	22
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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

JOHN M. COVERT
DIRECTOR
(202) 772-8623
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August 24, 2018

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Non-Provisional Utility Patent Application Under 37 C.F.R. § 1.53(b)
(Continuation of Appl. No. 15/274,772; Filing Date: September 23, 2016)
Appl. No. To Be Assigned; Filing Date: August 24, 2018
For: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON
SKIPPING AND METHODS OF USE THEREOF**
Applicant: The University of Western Australia
Our Ref: 4140.01500B0

Commissioner:

Transmitted herewith for appropriate action are the following documents:

1. Payment made via EFS-Web in the amount of \$2,855.00 (small entity) to cover:

\$2,000.00	Track 1 Filing Fee – Certification and Request for Prioritized Examination (Track 1);
\$70.00	Processing Fee - Certification and Request for Prioritized Examination (Track 1);
\$785.00	Patent Application Fee (including basic filing, search, and examination fees);
2. Utility Patent Application Transmittal (PTO/AIA/15);
3. Certification and Request for Prioritized Examination Under 37 C.F.R. § 1.102(e) (Track 1);
4. Authorization to Treat a Reply As Incorporating An Extension of Time Under 37 C.F.R. § 1.136(a)(3);
5. U.S. Utility Patent Application entitled:

**ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING
AND METHODS OF USE THEREOF**

and naming as inventors:

Stephen Donald WILTON, Sue FLETCHER, and Graham MCCLOREY

Commissioner for Patents
August 24, 2018
Page 2

the application containing:

- i. 66 pages of description prior to the claims;
 - ii. 1 page of claims (2 claims);
 - iii. a one (1) page abstract;
 - iv. 22 sheets of drawings: (Figures 1-22);
6. An Application Data Sheet (37 C.F.R. § 1.76);
 7. Sequence Listing (text file).

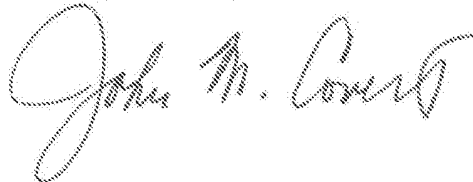
The above-listed documents are filed electronically through EFS-Web.

Correspondence should be sent to Customer No. 153767.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) or credit any overpayment to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert
Attorney for Applicant
Registration No. 38,759

JMC/NPS:dmc
Enclosures

9891263_1.docx

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 16112371

Document Date: 08/24/2018

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via eDAN using the Supplemental Content tab, or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: August 26, 2013

SRPT-VYDS-0005354

DocCode – SEQ.TXT

SCORE Placeholder Sheet for IFW Content

Application Number: 16112371

Document Date: 08/24/2018

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Sequence Listing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via eDAN using the Supplemental Content tab, or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: August 26, 2013

SRPT-VYDS-0005355

=====

Sequence Listing was accepted.

See attached Validation Report.

If you need help call the Patent Electronic Business Center at (866) 217-9197 (toll free).

Reviewer: Wheat Jr, Scott (ASRC)

Timestamp: [year=2018; month=8; day=29; hr=13; min=55; sec=4; ms=471;]

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Application No: 16112371 Version No: 1.0

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Output Set:

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Finished: 2018-08-24 18:02:30.759
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Total Errors: 1
No. of SeqIDs Defined: 214
Actual SeqID Count: 214

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Input Set:

Output Set:

Started: 2018-08-24 18:02:29.489
Finished: 2018-08-24 18:02:30.759
Elapsed: 0 hr(s) 0 min(s) 1 sec(s) 270 ms
Total Warnings: 212
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No. of SeqIDs Defined: 214
Actual SeqID Count: 214

Error code	Error Description
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SEQUENCE LISTING

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FLETCHER, SUE
MCCLOREY, GRAHAM

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OF USE THEREOF

<130> 4140.01500B0

<140> US 16/112,371

<141> 2018-08-24

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<151> 2016-09-23

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<151> 2015-06-15

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oligonucleotide

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: WILTON , S., et al.

Confirmation No.: 5407

Applicant: SAREPTA THERAPEUTICS

Art Unit: 1635

Application No.: 16/112,371

Examiner: CHONG, K.

Filing Date: August 24, 2018

Atty. Docket: 4140.01500B0

Title: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF**

Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a/b equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

- 2 -

STEPHEN DONALD WILTON
Application No. 16/112,371

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicant has checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement: (i) was first cited in any communication from a patent office in a counterpart¹ foreign or international application or from the Office; and this communication was not received by any individual designated in Sec. 1.56(c) more than thirty days prior to the filing of this information disclosure statement; OR (ii) is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in Sec. 1.56(c) more than thirty days prior to the filing of the information disclosure statement.
- ☐ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action

¹ The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application).

Atty. Dkt. No. 4140.01500B0

SRPT-VYDS-0005409

after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

- ☒ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
37 C.F.R. § 1.97(e)(1).

☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
37 C.F.R. § 1.97(e)(2).

☒ c. The required fee is provided through online credit card payment authorization in the amount of \$120.00 in payment of the fee under 37 C.F.R. § 1.17(p).

- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or

Notice of Allowance, but on or before payment of the Issue Fee. The required fee is provided through online credit card payment authorization in the amount of \$120.00 in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The patent family for one or more foreign language documents submitted herewith includes a United States patent, and other patent, in the English language. Copies of both the particular foreign patent(s) or published foreign patent applications cited in the foreign patent office communication, and that are not already of record in this application, are enclosed. Copies of the related United States or other English language patent or published application from the family list, if not already of record, are listed on the accompanying SB/08A form. For the purposes of a statement under 37 CFR 1.97(e)(1), the United States or

other English language patent or published application are to be construed as being cited by the foreign patent office. MPEP 609.04(b)(V).

- ☐ 6. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. MPEP 609.04(a)(III).
- ☐ 7. A concise explanation of the relevance of the non-English language document(s) appears below in accordance with 37 C.F.R. § 1.98(a)(3).
- ☒ 8. Copies of documents **NPL709-NPL713** are submitted. However, copies of documents **FP1-FP127** and **NPL1-NPL708** are not submitted. In addition, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of U.S. patents and patent application publications cited as documents US1-US219 on the attached IDS Forms are submitted.
- ☒ 9. Copies of the **FP1-FP127** and **NPL1-NPL708** documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 15/274,772, filed September 23, 2016, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).
- ☐ 10. It is expected that the examiner will review the prosecution and cited art in the parent Application No(s). _____ in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

- 6 -

STEPHEN DONALD WILTON
Application No. 16/112,371

- ☒ 11. In accordance with the Federal Circuit decision in *Dayco Prods., Inc. v. Total Containment, Inc.* 329 F.3d 1358 (Fed. Cir. 2003), Applicant submits herewith Office Actions from the co-pending U.S. Patent Application No. 15/645,842, filed July 10, 2017, as document **NPL709**; U.S. Patent Application No. 15/655,646, filed July 20, 2017, as documents **NPL710**; and U.S. Patent Application No. 15/673,019, filed August 9, 2017, as document **NPL711**. The identification of these Office Actions is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

Atty. Dkt. No. 4140.01500B0

SRPT-VYDS-0005413

- 7 -

STEPHEN DONALD WILTON
Application No. 16/112,371

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Neil P. Shull/

Neil P. Shull
Attorney for Applicant
Registration No. 60,238

Date: November 20, 2018

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Washington, D.C. 20005-3934
(202) 371-2600
10274917_1.docx

Atty. Dkt. No. 4140.01500B0

SRPT-VYDS-0005414

Doc code: IDS

33222

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number # 33223	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL1

Extended European Search Report, EP 17159328.8, dated September 5, 2017, 10 pages.

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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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33224

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	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US1	9506058		2016-11-29	Kaye	
	US2	9605262		2017-03-28	Wilton et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US3	20130190390	A1	2013-07-25	SAZANI et al.	
	US4	20170009233	A1	2017-01-12	WILTON et al.	

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	FP1	2013/142087	WO	A1	2013-09-26	Sarepta Therapeutics, Inc		

Application Number
33225

16/112,371

Filing Date

August 24, 2018

First Named Inventor

WILTON, Stephen

Art Unit

1635

Examiner Name

K. Chong

Attorney Docket Number

4140.01500B0

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(Not for submission under 37 CFR 1.99)

FP2	2014/172669	WO	A1	2014-10-23	Research Institute at Nationwide Children's Hosp.		
FP3	2017/059131	WO	A1	2017-04-06	Sarepta Therapeutics, Inc		

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	NPL2	GenBank AF213437.1 Dated January 17, 2002	
	NPL3	International Search Report and Written Opinion, PCT/US2016/054534, dated January 17, 2017, 13 pages.	
	NPL4	KOLE et al., "Exon skipping therapy for Duchenne muscular dystrophy," Advanced Drug Delivery Reviews, vol. 37:104-107 (2015).	
	NPL5	WHO Drug Information, International Nonproprietary Names for Pharmaceutical Substances (INN), Proposed INN: List 115, "CASIMERSEN," vol. 30(2): 3 pages (2016)	
	NPL6	WHO Drug Information, International Nonproprietary Names for Pharmaceutical Substances (INN), Proposed INN: List 115, "Golodirsen," vol. 30(2): 3 pages (2016)	

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33226

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US5	8436163		2013-05-07	Iversen et al.	
	US6	9416361		2016-08-16	Iversen et al.	

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	US7	20040266720	A1	2004-12-30	Iversen et al.	
	US8	20120053228	A1	2012-03-01	Iversen et al.	
	US9	20140045916	A1	2014-02-13	Iversen et al.	
	US10	20150232839	A1	2015-08-20	Iversen et al.	

Application Number **# 33227** 16/112,371
 Filing Date **August 24, 2018**
 First Named Inventor **WILTON, Stephen**
 Art Unit **1635**
 Examiner Name **K. Chong**
 Attorney Docket Number **4140.01500B0**

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 (Not for submission under 37 CFR 1.99)

	US11	20160298111	A1	2016-10-13	Bestwick et al.	
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33228

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
	Attorney Docket Number	4140.01500B0

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US12	9453225		2016-09-27	Sazani et al.	
	US13	9447417		2016-09-20	Sazani et al.	
	US14	9447416		2016-09-20	Sazani et al.	
	US15	9447415		2016-09-20	Wilton et al.	
	US16	9441229		2016-09-13	Wilton et al.	
	US17	9434948		2016-09-06	Sazani et al.	
	US18	9422555		2016-08-23	Wilton et al.	
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Application Number 16/112,371
 # 33229
 Filing Date August 24, 2018
 First Named Inventor WILTON, Stephen
 Art Unit 1635
 Examiner Name K. Chong
 Attorney Docket Number 4140.01500B0

**INFORMATION DISCLOSURE
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US19	20160177301	A1	2016-06-23	Wilton et al.	

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	NPL7	Errata to the Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Errata Document, NDA 206488, 5 pages.	
	NPL8	Extended European Search Report, EP 15190341.6, dated April 28, 2016, 9 pages.	
	NPL9	FDA Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen, NDA 206488, 115 pages	
	NPL10	FDA News Release, "FDA grants accelerated approval to first drug for Duchenne muscular dystrophy," September 19, 2016, 3 pages.	

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL11	Jett Foundation Presentation by McSherry, C. "Patient and Caregiver-Reported Outcomes of Patients in Clinical Trials of Eteplirsen for Treatment of Duchenne" at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 17 pages.
NPL12	Letter from the FDA to Sarepta Therapeutics, Inc., Re: ACCELERATED APPROVAL for the use of Exondys 51 (eteplirsen), FDA Reference ID: 3987286, dated September 19, 2016, 11 pages.
NPL13	Letter to the U.S. Food and Drug Administration, (Dr. Billy Dunn, M.D. Director Division of Neurology Products, Office of Drug Evaluation 1, Center for Drug Evaluation and Research), for The Peripheral and Central Nervous System Advisory Committee Meeting (AdComm) supporting approval of eteplirsen, dated February 24, 2016, 4 pages.
NPL14	Letter to the U.S. Food and Drug Administration, (Dr. Janet Woodcock, M.D. Director, CDER), from The Congress of The United States regarding Duchenne muscular dystrophy, dated February 17, 2016, 7 pages.
NPL15	Prescribing Information for EXONDYS 51 (eteplirsen) Injection, dated 09/2016, 10 pages
NPL16	Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Briefing Document, NDA 206488, 186 pages.
NPL17	Sarepta Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 133 pages
NPL18	Sarepta Press Release, Sarepta Issues Statement on Advisory Committee Outcome for Use of Eteplirsen in the Treatment of Duchenne Muscular Dystrophy, April 25, 2016, 2 pages
NPL19	Sarepta Therapeutics, Inc. News Release, "Sarepta Therapeutics Announces FDA Accelerated Approval of EXONDYS 51™ (eteplirsen) injection, an Exon Skipping Therapy to Treat Duchenne Muscular Dystrophy (DMD) Patients Amenable to Skipping Exon 51," September 19, 2016, 2 pages.
NPL20	U.S. Food and Drug Administration Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 178 pages.
NPL21	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 C.F.R. § 41.125(a), filed in Patent Interference No. 106008, September 20, 2016, pages 1-20 (Doc 480)

Application Number # 33231	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL22	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a) (Substitute), filed in Patent Interference No. 106007, May 12, 2016, pages 1-53 (Doc 476)
NPL23	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 C.F.R. § 41.127 filed in Patent Interference No. 106008, September 20, 2016, pages 1-3 (Doc 481)
NPL24	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 CFR § 41.127, filed in Patent Interference No. 106007, April 29, 2016, pages 1-3, (Doc 474)
NPL25	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecaration - 37 CFR 41.203(c), filed in Patent Interference No. 106007, April 29, 2016, pages 1-2, (Doc 473)
NPL26	University of Western Australia v. Academisch Ziekenhuis Leiden, Withdrawal and Reissue of Decision on Motions, filed in Patent Interference No. 106007, May 12, 2016, pages 1-2 (Doc 475)
NPL27	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a), filed in Patent Interference No. 106007, April 29, 2016, pages 1-53, (Doc 472)

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33232

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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	FP4	2000-325085	JP	A	2000-11-28	MATSUO MASAFUMI, ET AL.		
	FP5	2002-010790	JP	A	2002-01-15	MATSUO MASAFUMI, ET AL.		
	FP6	2002-325582	JP	A	2002-11-12	MATSUO, MASAFUMI, ET AL.		

Application Number
33233

16/112,371

Filing Date

August 24, 2018

First Named Inventor

WILTON, Stephen

Art Unit

1635

Examiner Name

K. Chong

Attorney Docket Number

4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

FP7	2002-340857	JP	A	2002-11-27	MATSUSHITA ELECTRIC IND CO LTD
FP8	2002-529499	JP	A	2002-09-10	ELI LILLY AND COMPANY
FP9	2004-509622	JP	A	2004-04-02	ACADEMISCH ZIEKENHUIS LEIDEN
FP10	2010-268815	JP	A	2010-12-02	MATSUO MASAFUMI
FP11	2011-101655	JP	A	2011-05-26	ACADEMISCH ZIEKENHUIS LEIDEN
FP12	2011-200235	JP	A	2011-10-13	ACADEMISCH ZIEKENHUIS LEIDEN
FP13	2014-054250	JP	A	2014-03-27	NIPPON SHINYAKU CO LTD.
FP14	2014-111638	JP	A	2014-06-19	ACADEMISCH, ZIEKENHUIS LEIDEN
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FP16	4777777	JP	B2	2011-09-21	KOBE UNIVERSITY
FP17	4846965	JP	B2	2011-12-28	ACADEMISCH ZIEKENHUIS LEIDEN

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FP21	00/44897	WO	A1	2000-08-03	AVI Biopharma, Inc.		
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FP47	2010/050802	WO	A2	2010-05-06	Academisch Ziekenhuis Leiden et al.	<input type="checkbox"/>
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 First Named Inventor WILTON, Stephen
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 Examiner Name K. Chong
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	NPL28	AON PS1966 Mass Spectrometry Data, Pages 8, Exhibit Number 1154 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL29	AON PS1966 UPLC Data, Pages 2, Exhibit Number 1165 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
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NPL34	AON PS229 (h53AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1142 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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NPL38	AON PS43 (h51AON1) HPLC Chromatogram, Pages 1, Exhibit Number 1131 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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NPL63	Brooke MH, et al., "Clinical investigation in Duchenne dystrophy: 2. Determination of the "power" of therapeutic trials based on the natural history," Muscle Nerve. 1983;6:91-103.
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NPL65	Bushby K, et al. "Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management," Lancet Neurol 2010;9:77-93.
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NPL70	Claim Chart 11/233,495, Pages 57, Exhibit Number 1216 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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NPL72	Claim Chart, US 7,807,816, 14 pages (Exhibit Number 1063 filed in interferences 106008, 106007 on November 18, 2014)
NPL73	Claim Chart, US 7,960,541, 17 pages (Exhibit Number 1064 filed in interferences 106008, 106007 on November 18, 2014)
NPL74	Claim Chart, US 8,455,636, 32 pages (Exhibit Number 1062 filed in interferences 106008, 106007 on November 18, 2014)
NPL75	Claim Comparison Chart - Claims 11 and 29 in 13/550,210, Pages 1, Exhibit Number 1226 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL76	Claim Comparison Chart 13/550,210 vs 11/233,495, Pages 12, Exhibit Number 1218 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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	FP56	2011/143008	WO	A1	2011-11-17	The Charlotte-Mecklenburg Hospital Authority D/B/A		

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FP72	94/02595	WO	A1	1994-02-03	Ribozyme Pharmaceuticals, Inc.	<input type="checkbox"/>
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	NPL78	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in Interferences 106008, 106013, 106007 on November 18, 2014)	
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First Named Inventor	WILTON, Stephen
Art Unit	1635
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 First Named Inventor **WILTON, Stephen**
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Attorney Docket Number	4140.01500B0

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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL208	Fourth Declaration of Erik Sontheimer, Ph.D. (Pursuant to Bd.R. 41.155(b)(2) and SO 155.1.3 and 155.1.4), dated March 9, 2015, (University of Western Australia Exhibit 2138, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
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NPL210	FRALEY, Robert et al., "New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids," Trends Biochem., Vol. 6:77-80 (1981)

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NPL213	GEBSKI, Bianca L. et al., "Morpholino antisense oligonucleotide induced dystrophin exon 23 skipping in mdx mouse muscle," Human Molecular Genetics, Vol. 12(15):1801-1811 (2003)
NPL214	Generic Method for Average Mass Determination Using LC-UV-MS in the Negative Mode, Pages 15, Exhibit Number 1145 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL215	Generic UPLC Purity Method for Oligonucleotides (19- to 25-mers), Pages 18, Exhibit Number 1156 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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NPL218	GlaxoSmithKline Press Release, Issued in London, UK, dated June 27, 2013 (5 pages), Exhibit Number 1202 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL219	GlaxoSmithKline, "GSK and Prosensa announce start of Phase III study of investigational Duchenne Muscular Dystrophy medication," press release, 6 pages, dated January 19, 2011 (Exhibit Number 2060 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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NPL228	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL229	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL230	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL231	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL232	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL233	Laboratory Notebook Entry: General RNA recovery, 1 Page, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
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Examiner Name	K. Chong
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NPL276	Muntoni F, et al., "Dystrophin and mutations: one gene, several proteins, multiple phenotypes," Lancet Neurol. 2003;2:731-40.
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NPL289	PD-10 Desalting Columns, Pages 12, Exhibit Number 1141 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL290	Popplewell, et al., Design of Phosphorodiamidate Morpholino Oligomers (PMOs) For the Induction of Exon Skipping of the Human DMD Gene, DSGT Poster, 2008, 1 page.
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NPL296	Poster Abstract Listing for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2137, filed April 3, 2015 in interferences 106007, 106008, and 106013, pages 1-11).
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NPL300	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL301	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL302	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL303	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
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NPL419	University of Western Australia v. Academisch Ziekenhuis Leiden, Amendment and Response, US Application No. 11/233,495, Filed 1/22/2014, 8 pages, (Exhibit Number 2117 filed in interferences 106,007 and 106, 008, on February 17, 2015.
NPL420	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,007, 15 pages, dated August 15, 2014 (Doc 15)
NPL421	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,008, 14 pages, dated August 21, 2014 (Doc 14)

Application Number	16/112,371 # 33279
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL422	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,013, 14 pages, dated October 27, 2014 (Doc 16)
NPL423	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Clean Copy of Claims and Sequence, filed in Patent Interference No. 106,013, 5 pages, dated October 15, 2014 (Doc 12)
NPL424	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Corrected Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 13)
NPL425	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,007 dated December 23, 2014 (Doc 240)
NPL426	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,008, dated December 23, 2014 (Doc 244)
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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL428	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, as of November 18, 2014, 9 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 212)
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NPL430	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,008, 8 pages, dated September 10, 2014 (Doc 15)
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NPL434	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 24 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 29)
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STATEMENT BY APPLICANT**
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Application Number # 33281	16/112,371
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Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL439	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 15, 2014 (Doc 11)
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NPL441	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated July 31, 2014, Interference No. 106,007, (Exhibit Number 2045 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)
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NPL443	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Motions- 37 CFR§ 41.125(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-12 (Doc 192).
NPL444	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Priority 37 CFR § 41.125 (a), 18 pages, Patent Interference No. 106,013, (Doc 196), dated September 29, 2015.
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NPL446	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Erik Sontheimer dated November 17, 2014, Exhibit 1012 filed in Patent Interference Nos. 106,007 and 106,008, 112 pages, filed November 18, 2014
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL450	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Matthew J.A. Wood, Patent Interference Nos. 106,007, 106,008 and 106,013, 184 pages, dated November 18, 2014 (Exhibit Number 2081 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL451	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 2, 3 and 4, 3 pages, Patent Interference No. 106,013, (Doc 135), dated November 25, 2015.
NPL452	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,007, (Doc 243), dated January 29, 2015.
NPL453	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,008, (Doc 247), dated January 29, 2015.
NPL454	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,013, (Doc 137), dated January 29, 2015.
NPL455	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,007, dated March 19, 2015 (Doc 416)
NPL456	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106013, (Doc 151), dated March 19, 2015.
NPL457	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,008, (Doc 424), dated March 19, 2015.
NPL458	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment-37 CFR § 41.127, 2 pages, Patent Interference No. 106,013, (Doc 197), dated September 29, 2015.
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NPL460	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 3 pages, dated September 26, 2014 (Doc 20)

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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STATEMENT BY APPLICANT**
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NPL461	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 6 pages, dated September 23, 2014 (Doc 19)
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NPL463	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Miscellaneous 37 C.F.R. 41.104(a), 2 pages, Patent Interference Nos. 106,007, 106,008, 106,013, dated November 14, 2014
NPL464	University of Western Australia v. Academisch Ziekenhuis Leiden, Order to Show Cause- 37 CFR§ 41.104(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-3 (Doc 193).
NPL465	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecclaration, Patent Interference No. 106,008, 2 pages, dated September 23, 2014 (Doc 19)
NPL466	University of Western Australia v. Academisch Ziekenhuis Leiden, Second Declaration of Matthew J. A. Wood, M.D., D. PHIL., Patent Interference Nos. 106,007 and 106,008, 78 pages, dated February 17, 2015 (Exhibit Number 2116 filed in interferences 106,007 and 106,008, on February 17, 2015.
NPL467	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Initial Settlement Discussions, 3 pages, Patent Interference No. 106,013, (Doc 136), dated December 30, 2014.
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Application Number # 33284	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL472	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-10 (Doc 456).
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NPL474	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106007, April 3, 2015, pages 1-10 (Doc 431).
NPL475	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106008, April 3, 2015, pages 1-10 (Doc 439).
NPL476	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106013, April 3, 2015, pages 1-10 (Doc 153).
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Application Number # 33285	16/112,371
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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NPL488	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in interference 106007, pages 1-28 (Doc 428).

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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NPL497	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-4 (Doc 457).
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Application Number # 33287	16/112,371
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

NPL500	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL501	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL502	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL503	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL504	Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL505	REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)
NPL506	REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)
NPL507	Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012, 2 pages, (Exhibit Number 1072 filed in Interferences 106008, 106007 on December 23, 2014)
NPL508	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL509	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).
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Art Unit	1635
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NPL512	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 7 pages, Patent Interference Nos. 106,008, dated December 12, 2014 (Doc 221)
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NPL514	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,007, 7 pages, dated September 10, 2014 (Doc 17)
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NPL516	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Miscellaneous Motion 1 (for authorization to file terminal disclaimer), 5 pages, Patent Interference No. 106,008, dated October 17, 2014 (Doc 22)
NPL517	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 U.S.C., section 112(a)), 40 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 210)
NPL518	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 § 112(a)) Patent Interference No. 106,008 (Doc 213), 38 Pages, on November 18, 2014
NPL519	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (To Maintain Interference between UWA US Patent No. 8,486,907 and AZL USSN 14/198,992), 45 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 133)
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

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NPL523	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 Requesting an additional interference between UWA U.S. Patent No. 8,455,636 and AZL USSN 14/248,279, 36 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 212)
NPL524	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)
NPL525	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 218)
NPL526	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, July 2, 2015, pages 1-16 (Doc 469).
NPL527	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, September 2, 2015, pages 1-18 (Doc 470).

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16/112,371 # 33290
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL528	US Application No. 14/248,279, 29 pages; excerpts of prosecution history including: Amendment under 37 CFR 1.312 dated September 19, 2014; Amendment in Response to Final Office Action dated August 7, 2014; Declaration under 37 CFR 1.132 dated May 26, 2014; Declaration under 37 CFR 1.132 dated May 27, 2014; Response dated June 3, 2014 (Exhibit Number 2057 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL529	US Application No. 13/550,210, 27 pages; excerpts of prosecution history including: Response and Amendment dated May 12, 2014; Response to Non-Final Office Action dated January 21, 2014; Second Preliminary Amendment dated January 3, 2013 (Exhibit Number 2055 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL530	US claim amendments for Application No. 13/550,210, 3 pages, dated May 12, 2014 (Exhibit Number 2078 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL531	US Claims for Application No. 12/976,381, 1 page, dated December 22, 2010 (Exhibit Number 2065 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL532	US Declaration of Richard K. Bestwick, for Application No. 11/570,691, 5 pages, dated June 15, 2010 (Exhibit Number 1044 filed in interferences 106008, 106007 on November 18, 2014)
NPL533	US E-mail from Patent Trial and Appeal Board to Danny Huntington, 2 pages, dated October 9, 2014 (Exhibit Number 2002 filed in interferences 106008 on October 17, 2014)
NPL534	US Non-Final Office Action for Application No. 11/570,691, 16 pages, dated March 15, 2010 (Exhibit Number 1042 filed in interferences 106008, 106007 on November 18, 2014)
NPL535	US Office Action for Application No. 13/271,080, 25 pages, dated July 30, 2012 (Exhibit Number 1048 filed in interferences 106008, 106007 on November 18, 2014)
NPL536	US Office Action for Application No. 13/550,210, 12 pages, dated September 27, 2013 (Exhibit Number 2080 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL537	US Office Action for Application No. 13/902,376, 7 pages, dated January 7, 2014 (Exhibit Number 1045 filed in interferences 106008, 106007 on November 18, 2014)
NPL538	US Patent Application No. 12/198,007 as-filed, 64 pages, dated August 25, 2008 (Exhibit Number 2092 filed in interferences 106008, 106013, and 106007 on November 18, 2014)

Application Number	16/112,371 # 33291
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

NPL539	US Preliminary Amendment and application as-filed for Application No. 12/976,381, 64 pages, dated December 22, 2010 (Exhibit No. 2089 filed in Interferences 106007, 106008, and 106013 on November 18, 2014)
NPL540	US Preliminary Amendment for Application No. 11/233,495, 10 pages, dated September 21, 2005 (Exhibit Number 2069 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL541	US Preliminary Remarks for Application No. 14/198,992, 1 page, dated March 6, 2014 (Exhibit Number 2097 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL542	US Proposed Terminal Disclaimer for Application No. 12/860,078, 2 pages, dated October 17, 2014 (Exhibit Number 2001 filed in interference 106008 on October 17, 2014)
NPL543	US Remarks for Application No. 14/248,279, 2 pages, dated August 27, 2014 (Exhibit Number 2110 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL544	US Response and amendments for Application No. 13/550,210, 12 pages, dated January 21, 2014 (Exhibit Number 2063 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL545	US Revised Figure 4H, US Application No. 13/271,080, 1 page (Exhibit Number 1050 filed in interferences 106008, 106007 on November 18, 2014)
NPL546	US Terminal Disclaimer for Application No. 14/198,992, 1 page, dated July 15, 2014 (Exhibit Number 2096 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL547	US Terminal Disclaimer for Application No. 14/248,279, 1 page, dated August 7, 2014 (Exhibit Number 2109 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL548	US Track One Request, Application as-filed, and Application Data Sheet for Application No. 14/248,279, 68 pages, dated April 8, 2014 (Exhibit Number 2108 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL549	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 11/570,691, 102 pages, dated December 15, 2006 (Exhibit Number 2103 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number	16/112,371 # 33292
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL550	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/270,992, 101 pages, dated October 11, 2011 (Exhibit Number 2098 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL551	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/271,080, 115 pages, dated October 11, 2011 (Exhibit Number 2111 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL552	US Updated Filing Receipt for Application No. 13/550,210, 3 pages, dated December 11, 2012 (Exhibit Number 2044 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL553	USPTO "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving...Natural Products" ("the March Guidance"), 19 pages, (Exhibit Number 2118 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL554	USPTO Written Description Training Materials, Revised March 25, 2008, Example 12, 6 pages, (Exhibit Number 1068 filed in interferences 106008, 106007 on December 23, 2014)
NPL555	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 1, 2014 (Paper 12), 8 pages, (Exhibit Number 2126 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL556	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 7, 2014 (Paper 12), 8 pages, (Exhibit Number 2127 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL557	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,007 (PN210), 40 Pages, Exhibit Number 1005 filed in Interference 106,013 on February 17, 2015.
NPL558	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,008 (Doc 213), Pages 38, Exhibit Number 1004 filed in Interference 106,013 on February 17, 2015.
NPL559	JWA submission of teleconference transcript , 28 pages, dated December 12, 2014 (Exhibit Number 2114 filed in interferences 106008 and 106007 on December 12, 2014)
NPL560	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

NPL561	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in Interferences 106008, 106007 on December 23, 2014)
NPL562	van Deutekom et al., "Local Dystrophin Restoration with Antisense Oligonucleotide PRO051," N. Engl. J. Med., Vol. 357, No. 26, pp. 2677-2686 (December, 2007), Exhibit Number 1213 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL563	VAN DEUTEKOM, Judith C. T. et al., "Advances in Duchenne Muscular Dystrophy Gene Therapy," Nature Reviews Genetics, Vol. 4(10):774-783 (2003)
NPL564	van Ommen 2002 PCT (WO 02/24906 A1), 43 pages,(Exhibit Number 1071 filed in Interferences 106008, 106007 on December 23, 2014)
NPL565	van Putten M, et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages
NPL566	Van Vliet, Laura et al., "Assessment of the Feasibility of Exon 45-55 Multiexon Skipping for Duchenne Muscular Dystrophy", BMC Medical Genetics, Vol.9(1):105 (2008)
NPL567	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in Interferences 106008, 106007 on November 18, 2014)
NPL568	Vikase Corp. v. Am. Nat'l. Can Co., No. 93-7651, 1996 WL 377054 (N.D. Ill. July 1, 1996), 3 pages (Exhibit Number 2152 filed in interference 106013 on October 29, 2015)
NPL569	VOIT, Thomas et al., "Safety and efficacy of drisapersen for the treatment of Duchenne muscular dystrophy (DEMAND 1): an exploratory, randomised, placebo-controlled phase 2 study," Lancet Neurol., Vol. 13:987-996 (2014) (Exhibit Number 2037 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL570	VOLLOCH, Vladimir et al., "Inhibition of Pre-mRNA Splicing by Antisense RNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons," Biochemical and Biophysical Research Communications, Vol. 179 (3):1593-1599 (1991)
NPL571	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL572	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, July 2, 2015, pages 1-16 (Doc 477).
NPL573	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, September 2, 2015, pages 1-18 (Doc 478).
NPL574	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 11)
NPL575	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,008, 5 pages, dated August 7, 2014 (Doc 11)
NPL576	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 14, 2014 (Doc 6)
NPL577	JS 7,960,541 (Wilton et al.), Pages 84, Exhibit Number 1002 filed in interferences 106,007 and 106,008 on November 18, 2014.
NPL578	JS 8,450,474 (Wilton et al.), Pages 95, Exhibit Number 1087 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL579	JS 8,455,634 (Wilton et al.) Pages 96, Exhibit Number 1088 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL580	JS 8,455,635 (Wilton et al.), Pages 96, Exhibit Number 1089 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL581	JS 8,455,636 (Wilton et al.), Pages 92, Exhibit Number 1003 filed in interferences 106,007 and 106,008 on November 18, 2014.
NPL582	JS 8,476,423 (Wilton et al.), Pages 95, Exhibit Number 1111 filed in interferences 106,007 and 106,008 on February 13, 2015.

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Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL583	US 8,501,703 (Bennett et al.), Pages 16, Exhibit Number 1090 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL584	US 8,501,704 (Mourich et al.), Pages 39, Exhibit Number 1091 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL585	US 8,524,676 (Stein et al.), Pages 28, Exhibit Number 1092 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL586	US 8,524,880 (Wilton et al.), Pages 89, Exhibit Number 1093 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL587	US 8,536,147 (Weller et al.), Pages 95, Exhibit Number 1094 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL588	US 8,592,386 (Mourich et al.), Pages 46, Exhibit Number 1095 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL589	US 8,618,270 (Iversen et al.), Pages 28, Exhibit Number 1096 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL590	US 8,637,483 (Wilton et al.), Pages 157, Exhibit Number 1097 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL591	US 8,697,858 (Iversen), Pages 95, Exhibit Number 1098 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL592	US 8,703,735 (Iversen et al.) Pages 73, Exhibit Number 1099 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL593	US 8,741,863 (Moulton et al.), Pages 68, Exhibit Number 1100 filed in interferences 106,007 and 106,008 on February 13, 2015.

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Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL594	JS 8,759,307 (Stein et al.), Pages 35, Exhibit Number 1101 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL595	JS 8,779,128 (Hanson et al.), Pages 104, Exhibit Number 1102 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL596	JS 8,785,407 (Stein et al.), Pages 35, Exhibit Number 1103 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL597	JS 8,785,410 (Iversen et al.), Pages 20, Exhibit Number 1104 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL598	JS 8,835,402 (Kole et al.), Pages 27, Exhibit Number 1105 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL599	JS 8,865,883 (Sazani et al.), Pages 199, Exhibit Number 1106 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL600	JS 8,871,918 (Sazani et al.), Pages 195, Exhibit Number 1107 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL601	JS 8,877,725 (Iversen et al.), Pages 34, Exhibit Number 1108 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL602	JS 8,895,722 (Iversen et al.), Pages 29, Exhibit Number 1109 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL603	JS 8,906,872 (Iversen et al.), Pages 69, Exhibit Number 1110 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL604	JS Abandonment for Application No. 13/902,376, 1 page, dated June 12, 2014 (Exhibit Number 1047 filed in interferences 106008, 106007 on November 18, 2014)

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL605	US Amendment After Non-Final Action for Application No. 11/233,495, 31 pages, dated June 24, 2010 (Exhibit Number 2073 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL606	US Amendment for Application No. 11/233,495, 15 pages, dated April 1, 2009 (Exhibit Number 2071 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL607	US Amendment for Application No. 11/233,495, 19 pages, dated September 16, 2009 (Exhibit Number 2072 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL608	US Amendment for Application No. 11/233,495, 9 pages, dated October 31, 2007 (Exhibit Number 2070 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL609	US Amendment for Application No. 11/570,691, 9 pages, dated June 15, 2010 (Exhibit Number 1043 filed in interferences 106008, 106007 on November 18, 2014)
NPL610	US Amendment for Application No. 13/271,080, 30 pages, dated January 30, 2013 (Exhibit Number 1049 filed in interferences 106008, 106007 on November 18, 2014)
NPL611	US Amendment for Application No. 13/902,376, 36 pages, dated March 21, 2014 (Exhibit Number 1046 filed in interferences 106008, 106007 on November 18, 2014)
NPL612	US Amendment in Response to Advisory Action for Application No. 11/233,495, 23 pages, dated March 14, 2011 (Exhibit Number 2074 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL613	US Amendments to the Claims for Application No. 11/233,495, 4 pages, dated May 8, 2014 (Exhibit Number 2077 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL614	US Amendments to the Claims for Application No. 14/198,992, 3 pages, dated July 16, 2014 (Exhibit Number 2079 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL615	US Applicant-Initiated Interview Summary and Notice of Allowance for Application No. 13/550,210, 9 pages dated May 19, 2014 (Exhibit Number 2076 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number # 33298	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

NPL616	US application as-filed and Preliminary Amendment for Application No. 13/550,210, 59 pages dated July 16, 2012 (Exhibit Number 2087 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL617	US Application as-filed for application No. 14/198,992, 52 pages, dated March 6, 2014 (Exhibit Number 2086 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL618	US Application as-filed, Application Data Sheet, and Preliminary Amendment for Application No. 12/837,359, 101 pages, dated July 15, 2010 (Exhibit Number 2100 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL619	US Application for Letters Patent for Application No. 11/233,495 as-filed and preliminary amendment, 77 pages, dated September 21, 2005 (Exhibit Number 2095 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL620	US Application No. 11/233,495, 74 pages; excerpts of prosecution history including: US Supplemental Amendment and Response dated May 8, 2014; Second Supplemental Response dated July 25, 2013; Supplemental Amendment dated June 26, 2013; Amendment after Non-final Action dated November 1, 2010; Amendment under 35 USC 1.114 dated September 16, 2009 (Exhibit Number 2054 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL621	US Application No. 14/198,992, 17 pages; excerpts of prosecution history including: Supplemental Amendment dated July 16, 2014; Response to Non-Final Office Action dated July 14, 2014 (Exhibit Number 2056 filed in interferences 106008, 106013, 106007 on November 18, 2014)

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33299

PTO/SB/08a (03-15)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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Application Number	16/112,371 # 33300
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL622	WILTON, Stephen D. et al., "Antisense oligonucleotides in the treatment of Duchenne muscular dystrophy: where are we now?" Neuromuscular Disorders, Vol. 15:399-402 (2005)
NPL623	WILTON, Stephen D. et al., "Specific removal of the nonsense mutation from the mdx dystrophin mRNA using antisense oligonucleotides," Neuromuscular Disorders, Vol. 9:330-338 (1999)
NPL624	WO 2002/24906 A1 of AZL, (University of Western Australia Exhibit 2134, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-43.)
NPL625	WO 2004/083432 (the published AZL PCT Application, "Van Ommen"), Pages 71, Exhibit Number 1003 filed in interference 106,013 on February 17, 2015.
NPL626	WO 2013/112053 A1, (University of Western Australia Exhibit 2130, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-177).
NPL627	WOLFF, Jon A. et al., "Direct Gene Transfer into Mouse Muscle in Vivo," Science, Vol. 247:1465-1468 (1990)
NPL628	WONG, Marisa L. et al., "Real-time PCR for mRNA quantitation," BioTechniques, Vol. 39:75-85 (2005) (Exhibit Number 1066 filed in interferences 106008, 106007 on November 18, 2014)
NPL629	Wood, "Toward an Oligonucleotide Therapy for Duchenne Muscular Dystrophy: A Complex Development Challenge," Science Translational Medicine, Vol. 2, No. 25, pp. 1-6 (March, 2010), Exhibit Number 1116 filed in interferences 106,007 and 106,008 on February 17, 2015, Doc 335.
NPL630	Written Opinion for Application No. PCT/AU2010/001520, 6 pages, dated January 21, 2011
NPL631	WU, B. et al., "Dose-dependent restoration of dystrophin expression in cardiac muscle of dystrophic mice by systemically delivered morpholino," Gene Therapy, Vol. 17:132-140 (2010)
NPL632	WU, Bo et al., "Effective rescue of dystrophin improves cardiac function in dystrophin-deficient mice by a modified morpholino oligomer," PNAS, Vol. 105(39):14814-14819 (2008)

Application Number	16/112,371 # 33301
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL633	WU, Bo et al., "Targeted Skipping of Human Dystrophin Exons in Transgenic Mouse Model Systemically for Antisense Drug Development," PLoS One, Vol. 6(5):e19906, 11 pages (2011)
NPL634	WU, George Y. et al., "Receptor-mediated Gene Delivery and Expression in Vivo," The Journal of Biological Chemistry, Vol. 263(29):14621-14624 (1988)
NPL635	WU, George Y. et al., "Receptor-mediated in Vitro Gene Transformation by a Soluble DNA Carrier System," The Journal of Biological Chemistry, Vol. 262(10):4429-4432 (1987)
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Doc code: IDS

33302

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Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
	Attorney Docket Number	4140.01500B0

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Examiner Name	K. Chong	
Attorney Docket Number	4140.01500B0	

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 First Named Inventor WILTON, Stephen
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Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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FP101	2284264	EP	A1	2011-02-16	ACADEMISCH ZIEKENHUIS LEIDEN		

Application Number # 33523	16/112,371
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First Named Inventor	WILTON, Stephen
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FP118	2607484	EP	A1	2013-06-26	PROSENSA TECHNOLOGIES B.V.		
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FP120	2614827	EP	A2	2013-07-17	ACADEMISCH ZIEKENHUIS LEIDEN		
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 First Named Inventor WILTON, Stephen
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 Examiner Name K. Chong
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Application Number # 33326	16/112,371
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First Named Inventor	WILTON, Stephen
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**INFORMATION DISCLOSURE
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Application Number # 33328	16/112,371
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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(Not for submission under 37 CFR 1.99)

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NPL691

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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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Electronic Patent Application Fee Transmittal				
Application Number:		16112371		
Filing Date:		24-Aug-2018		
Title of Invention:		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
First Named Inventor/Applicant Name:		Stephen Donald WILTON		
Filer:		Neil P. Shull/Tamara Haynesworth		
Attorney Docket Number:		4140.01500B0		
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Application Number:	16112371
International Application Number:	
Confirmation Number:	5407
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First Named Inventor/Applicant Name:	Stephen Donald WILTON
Customer Number:	153767
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Information:					
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12	Terminal Disclaimer Filed	2018-11-20-Terminal-Disclaimer-4140-01500B0_1.PDF	172121 09736205c754c8b12664b89688cc48051ab3a83e	no	2

Warnings:**Information:**

13	Terminal Disclaimer Filed	2018-11-20-Terminal-Disclaimer-4140-01500B0_2.PDF	253424	no	2
			371fc5c54f258fd724b3f538549a7b9184e3cd3		

Warnings:**Information:**

14	Terminal Disclaimer Filed	2018-11-20-Terminal-Disclaimer-4140-01500B0_3.PDF	166991	no	2
			e86ed3a9350663832c2274d2908a01a01b6360f8		

Warnings:**Information:**

15	Fee Worksheet (SB06)	fee-info.pdf	32271	no	2
			a1963277bdcbb1d719098b3914133454758be103		

Warnings:**Information:**

Total Files Size (in bytes):			73081187		
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PA..
Document Description: Power of Attorney

8319.53.US46T1

PTO/AIA/82B (07-13)

Approved for use through 01/31/2018, OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
16/112,371	August 24, 2018

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

153767

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

153767

OR

☐ Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

THE UNIVERSITY OF WESTERN AUSTRALIA

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature *Robyn Owens*

Date (Optional) - 6 DEC 2018

Name Professor Robyn Owens

Title Deputy Vice-Chancellor (Research)

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: The University of Western Australia

Application No./Patent No.: 16/112,371 Filed/Issue Date: August 24, 2018

Titled: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

The University of Western Australia, a university

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is ____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 047702, Frame 0442, or for which a copy thereof is attached.
- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

SRPT-VYDS-0005604

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Eric K. Steffe Reg. No. 36,688/

December 10, 2018

Signature

Date

Eric K. Steffe

36,688

Printed or Typed Name

Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	34534705
Application Number:	16112371
International Application Number:	
Confirmation Number:	5407
Title of Invention:	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Stephen Donald WILTON
Customer Number:	153767
Filer:	Neil P. Shull/Debbie Colonna
Filer Authorized By:	Neil P. Shull
Attorney Docket Number:	4140.01500B0
Receipt Date:	10-DEC-2018
Filing Date:	24-AUG-2018
Time Stamp:	14:53:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	4140_01500B0_TD_8232384.pdf	142493 db035474a372dfef3913bfedd917494c38a03f50	no	2

Warnings:

Information:					
2	Terminal Disclaimer Filed	4140_01500B0_TD_9994851.pdf	142848 b232ae01d6861c6d0d629578187b9da003ef578f	no	2
Warnings:					
Information:					
3	Terminal Disclaimer Filed	4140_01500B0_TD_15645842.pdf	210607 7501fbc39971fbb8533cb1618df340bd18e425c6	no	2
Warnings:					
Information:					
4	Power of Attorney	4140_01500B0_executed_POA.pdf	1986438 10634e6305bc324711a712d24afc47493e84ee67	no	1
Warnings:					
Information:					
5	Assignee showing of ownership per 37 CFR 3.73	4140_01500B0_Statement_373c.pdf	81203 6549ed66019da9803cca125a38a1c2fa5198061	no	3
Warnings:					
Information:					
Total Files Size (in bytes):			2563589		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/112,371	08/24/2018	Stephen Donald WILTON	4140.01500B0

CONFIRMATION NO. 5407

POA ACCEPTANCE LETTER

153767
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005



OC00000010441222

Date Mailed: 12/13/2018

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/10/2018.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/hteffer/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

153767 7590 01/03/2019
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
 1100 NEW YORK AVENUE, N.W.
 WASHINGTON, DC 20005

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 01/03/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/112,371	08/24/2018	Stephen Donald WILTON	4140.01500B0	5407

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	04/03/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL
#: 33347

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

153767 7590 01/03/2019
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/112,371	08/24/2018	Stephen Donald WILTON	4140.01500B0	5407

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	04/03/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1635	514-044000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47: Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
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 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/112,371	08/24/2018	Stephen Donald WILTON	4140.01500B0	5407
153767	7590	01/03/2019		
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 01/03/2019

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

#: 33849

<p align="center"><i>Notice Requiring Inventor's Oath or Declaration</i></p>	Application No. 16/112,371	Applicant(s) Stephen Donald WILTON	
	Examiner CHONG, KIMBERLY	Art Unit 1635	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) **MUST** be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- A properly executed inventor's oath or declaration has not been received for the following inventor(s): **Stephen Donald WILTON, Sue Fletcher, and Graham McClorey.**

Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/112,371	Applicant(s) WILTON et al.	
	Examiner KIMBERLY CHONG	Art Unit 1635	AIA Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/10/2018.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-2. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☒ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 11570691.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file areply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>12/10/2018</u> . 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date. _____.	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
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/KIMBERLY CHONG/
Primary Examiner, Art Unit 1635

Application/Control Number: 16/112,371
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Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance: the double patenting rejections of record have been overcome with Terminal Disclaimers filed 12/10/2018.

The claims are in condition for allowance.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 11/20/2018 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **KIMBERLY CHONG** at (571)272-3111. The examiner can normally be reached Monday thru Friday between M-F 8:00am-4:30pm.

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Art Unit: 1635

Page 3

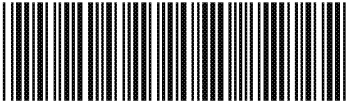
If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Ram Shukla at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635

33354

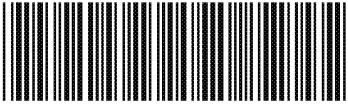
Issue Classification 	Application/Control No. 16/112,371	Applicant(s)/Patent Under Reexamination WILTON et al.
	Examiner KIMBERLY CHONG	Art Unit 1635

CPC						
Symbol					Type	Version
C12N	/	15	/	113	F	2013-01-01
C12N	/	2320	/	30	A	2013-01-01
C12N	/	2310	/	3341	A	2013-01-01
C12N	/	2310	/	321	A	2013-01-01
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C12N	/	2310	/	11	A	2013-01-01
C12N	/	2320	/	33	A	2013-01-01
C12N	/	2310	/	3519	A	2013-01-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version
/				

NONE	Total Claims Allowed:	
(Assistant Examiner)	(Date)	2
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1635	20 December 2018	O.G. Print Claim(s)
(Primary Examiner)	(Date)	1
		O.G. Print Figure
		none

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Issue Classification 	Application/Control No. 16/112,371	Applicant(s)/Patent Under Reexamination WILTON et al.
	Examiner KIMBERLY CHONG	Art Unit 1635

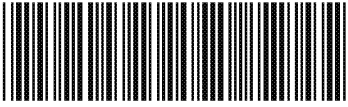
INTERNATIONAL CLASSIFICATION			
CLAIMED			
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NON-CLAIMED			
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US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
536	24.5

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	2	
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1635	20 December 2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

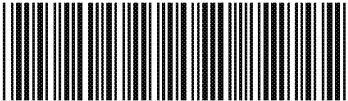
33356

Issue Classification 	Application/Control No. 16/112,371	Applicant(s)/Patent Under Reexamination WILTON et al.
	Examiner KIMBERLY CHONG	Art Unit 1635

<input checked="" type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input checked="" type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)		Total Claims Allowed: 2	
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1635 (Primary Examiner)		20 December 2018 (Date)	O.G. Print Claim(s) 1
			O.G. Print Figure none

33357

<i>Search Notes</i> 	Application/Control No. 16/112,371	Applicant(s)/Patent Under Reexamination WILTON et al.
	Examiner KIMBERLY CHONG	Art Unit 1635

CPC - Searched*		
Symbol	Date	Examiner
C07H 2104	10/12/2018	KC

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
C07H 2104	10/12/2018	KC
SEQ 195 search	10/12/2018	KC
PALM inventor name search	10/12/2018	KC
updated	12/19/2018	KC

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
536	24.5	12/19/2018	KC

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Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL222	GORDON, Peter M. et al., "Metal ion catalysis during the exon-ligation step of nuclear pre-mRNA splicing: Extending the parallels between the spliceosome and group II introns," RNA, Vol. 6:199-205 (2000) (Exhibit Number 1055 filed in interferences 106008, 106007 on November 18, 2014)
NPL223	Gordon, Peter M., et al., "Kinetic Characterization of the Second Step of Group II Intron Splicing: Role of Metal Ions and the Cleavage Site 2'-OH in Catalysis," Biochemistry, Vol. 39, pp. 12939-12952 (2000), Exhibit Number 1188 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL224	GOYENVALLE, Aurelie et al., "Prevention of Dystrophic Pathology in Severely Affected Dystrophin/Utrophin-deficient Mice by Morpholino-oligomer-mediated Exon-skipping," Molecular Therapy, Vol. 18(1):198-205 (2010)
NPL225	HAMMOND, Suzan M. et al., "Correlating In Vitro Splice Switching Activity With Systemic In Vivo Delivery Using Novel ZEN-modified Oligonucleotides," Molecular Therapy - Nucleic Acids, Vol. 3:1, 11 pages (2014) (Exhibit Number 2011 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL226	Hammond, Suzan M., et al., "Genetic therapies for RNA mis-splicing diseases," Cell, Vol.27, No. 5, pp. 196-205 (May, 2011), Exhibit Number 1113 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL227	Hammond, Suzan M., et al., "PRO-051, an antisense oligonucleotide for the potential treatment of Duchenne muscular dystrophy," Curr. Opinion Mol. Therap., Vol. 12, No. 4, pp. 478-486 (2010), Exhibit Number 1121 filed in interferences 106,007 and 106,008 on February 13, 2015.

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Application Number # 33359	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL228	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL229	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL230	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL231	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL232	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL233	Laboratory Notebook Entry: General RNA recovery, 1 Page, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL234	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL235	Larsen et al., "Antisense properties of peptide nucleic acid," Biochim. Et Biophys. Acta, Vol. 1489, pp. 159-166 (1999), Exhibit Number 1190 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL236	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL237	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)
NPL238	Lu et al, "Massive Idiosyncratic Exon Skipping Corrects the Nonsense Mutation in Dystrophic Mouse Muscle and Produces Functional Revertant Fibers by Clonal Expansion," THE JOURNAL OF CELL BIOLOGY, Vol. 148(5): 985-995, March 6, 2000 ("Lu et al.") (Exhibit Number 1082 filed in interferences 106008, 106007 on December 23, 2014)

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL239	LU, Qi Long et al., "Functional amounts of dystrophin produced by skipping the mutated exon in the mdx dystrophic mouse," Nature Medicine, Vol. 9(8):1009-1014 (2003)
NPL240	LU, Qi-long et al., "What Can We Learn From Clinical Trials of Exon Skipping for DMD?" Molecular Therapy - Nucleic Acids, Vol. 3:e152, doi:10.1038/mtna.2014.6, 4 pages (2014)
NPL241	Lyophilisation of Oligonucleotides, Pages 2, Exhibit Number 1133 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL242	MANN, Christopher J. et al., "Antisense-induced exon skipping and synthesis of dystrophin in the mdx mouse," PNAS, Vol. 98(1):42-47 (2001)
NPL243	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," The Journal of Gene Medicine, Vol. 4:644-654 (2002)
NPL244	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," BioTechniques, Vol. 6(7):682-690 (1988)
NPL245	Manual of Patent Examining Procedure 2308.02 (6th ed., rev. 3, July 1997), (University of Western Australia Exhibit 2143, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).
NPL246	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," Cochrane Database Syst Rev. 2004;(2):CD003725.
NPL247	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," Journal of Immunological Methods, Vol. 325:114-126 (2007)
NPL248	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol. 288:911-940 (1999), (University of Western Australia Exhibit 2131, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-31).
NPL249	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol., Vol. 288, pp. 911-940 (1999), Exhibit Number 1212 filed in Interferences 106,007 and 106,008 on February 17, 2015.

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL250	MATSUO, Masafumi et al., "Exon Skipping during Splicing of Dystrophin mRNA Precursor due to an Intraexon Deletion in the Dystrophin Gene of Duchenne Muscular Dystrophy Kobe," J. Clin. Invest., Vol. 87:2127-2131 (1991)
NPL251	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," Basic Appl. Myol., Vol. 13(6):281-285 (2003)
NPL252	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," JMBB Life, Vol. 53:147-152 (2002)
NPL253	MATSUO, Masafumi, "Duchenne/Becker muscular dystrophy: from molecular diagnosis to gene therapy," Brain & Development, Vol. 18:167-172 (1996)
NPL254	MATTEUCCI, Mark, "Structural modifications toward improved antisense oligonucleotides," Perspectives in Drug Discovery and Design, Vol. 4:1-16 (1996)
NPL255	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.
NPL256	MCCARVILLE, M. Beth et al., "Rhabdomyosarcoma in Pediatric Patients: The Good, the Bad, and the Unusual," AJR, Vol. 176:1563-1569 (2001) (Exhibit Number 1034 filed in interferences 106008, 106007 on November 18, 2014)
NPL257	McCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)
NPL258	McCLOREY, G. et al., "Induced dystrophin exon skipping in human muscle explants," Neuromuscular Disorders, Vol. 16:583-590 (2006)
NPL259	McCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)
NPL260	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92

Application Number # 33362	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL261	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.
NPL262	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.
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NPL369	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).
NPL370	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).
NPL371	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).

Application Number	16/112,371 # 33373
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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NPL372	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL373	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL374	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in Interferences 106008, 106007 on December 23, 2014)
NPL375	U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in Interferences 106008, 106007 on December 23, 2014)
NPL376	U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") 10 pages, (Exhibit Number 1080 filed in Interferences 106008, 106007 on December 23, 2014)
NPL377	U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al.") 50 pages, (Exhibit Number 1081 filed in Interferences 106008, 106007 on December 23, 2014)

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Examiner Signature		Date Considered	
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL378	J.S. Patent No. 5,190,931 ("the '931 Patent") 22 pages,(Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)
NPL379	J.S. Patent No. 7,001,761 (the "Xiao" Patent) 64 pages, (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)
NPL380	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.
NPL381	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007and 106008, pages 1-15.
NPL382	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).
NPL383	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).
NPL384	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.
NPL385	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.
NPL386	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.
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NPL388	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.

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First Named Inventor	WILTON, Stephen
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Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL389	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015
NPL390	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015
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NPL392	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015
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NPL394	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. § 135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015
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NPL396	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).
NPL397	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).
NPL398	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).
NPL399	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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NPL400	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).
NPL401	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).
NPL402	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).
NPL403	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).
NPL404	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).
NPL405	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).
NPL406	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.
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NPL408	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Statement Regarding Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 189).
NPL409	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,007, May 5, 2015, pages 1-18 (Doc 466).
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STATEMENT BY APPLICANT**
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NPL411	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,007, May 5, 2015, pages 1-22 (Doc 465).
NPL412	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,008, May 5, 2015, pages 1-21 (Doc 473).
NPL413	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,007, May 28, 2015, pages 1-3, (Doc 468)
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NPL415	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,013, May 28, 2015, pages 1-3, (Doc 491)
NPL416	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, DOC 149, Patent Interference No. 106,013 dated February 23, 2015.
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NPL418	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 421, Patent Interference No. 106,008 dated February 23, 2015.
NPL419	University of Western Australia v. Academisch Ziekenhuis Leiden, Amendment and Response, US Application No. 11/233,495, Filed 1/22/2014, 8 pages, (Exhibit Number 2117 filed in interferences 106,007 and 106, 008, on February 17, 2015.
NPL420	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,007, 15 pages, dated August 15, 2014 (Doc 15)
NPL421	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,008, 14 pages, dated August 21, 2014 (Doc 14)

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL422	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,013, 14 pages, dated October 27, 2014 (Doc 16)
NPL423	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Clean Copy of Claims and Sequence, filed in Patent Interference No. 106,013, 5 pages, dated October 15, 2014 (Doc 12)
NPL424	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Corrected Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 13)
NPL425	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,007 dated December 23, 2014 (Doc 240)
NPL426	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,008, dated December 23, 2014 (Doc 244)
NPL427	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, 9 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 209)

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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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NPL429	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,007, 6 pages, dated September 10, 2014 (Doc 16)
NPL430	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,008, 8 pages, dated September 10, 2014 (Doc 15)
NPL431	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 181)
NPL432	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 184)
NPL433	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 23 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 26)
NPL434	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 24 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 29)
NPL435	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad) 20 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 30)
NPL436	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad), 19 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 27)
NPL437	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated July 31, 2014 (Doc 6)
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL440	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated August 5, 2014, Interference No. 106,008, (Exhibit Number 2047 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)
NPL441	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated July 31, 2014, Interference No. 106,007, (Exhibit Number 2045 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)
NPL442	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated October 15, 2014., Interference No. 106,013, (Exhibit Number 2050 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)
NPL443	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Motions- 37 CFR§ 41.125(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-12 (Doc 192).
NPL444	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Priority 37 CFR § 41.125 (a), 18 pages, Patent Interference No. 106,013, (Doc 196), dated September 29, 2015.
NPL445	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision-Rehearing -37 CFR § 41.125(c), filed in Patent Interference No. 106,013, December 29, 2015, pages 1-12 (Doc 202).
NPL446	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Erik Sontheimer dated November 17, 2014, Exhibit 1012 filed in Patent Interference Nos. 106,007 and 106,008, 112 pages, filed November 18, 2014
NPL447	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,007, 7 pages, dated July 18, 2014 (Doc 1)
NPL448	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,008, 7 pages, dated July 24, 2014 (Doc 1)
NPL449	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,013, 8 pages, dated September 29, 2014 (Doc 1)

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First Named Inventor	WILTON, Stephen
Art Unit	1635
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL450	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Matthew J.A. Wood, Patent Interference Nos. 106,007, 106,008 and 106,013, 184 pages, dated November 18, 2014 (Exhibit Number 2081 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL451	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 2, 3 and 4, 3 pages, Patent Interference No. 106,013, (Doc 135), dated November 25, 2015.
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NPL453	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,008, (Doc 247), dated January 29, 2015.
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NPL455	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,007, dated March 19, 2015 (Doc 416)
NPL456	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106013, (Doc 151), dated March 19, 2015.
NPL457	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,008, (Doc 424), dated March 19, 2015.
NPL458	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment-37 CFR § 41.127, 2 pages, Patent Interference No. 106,013, (Doc 197), dated September 29, 2015.
NPL459	University of Western Australia v. Academisch Ziekenhuis Leiden, Miscellaneous Order under 37 CFR 41.104(a), 4 pages, Patent Interference Nos. 106,007 and 106,008, dated December 15, 2014
NPL460	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 3 pages, dated September 26, 2014 (Doc 20)

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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NPL461	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 6 pages, dated September 23, 2014 (Doc 19)
NPL462	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,008, 6 pages, dated September 23, 2014 (Doc 18)
NPL463	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Miscellaneous 37 C.F.R. 41.104(a), 2 pages, Patent Interference Nos. 106,007, 106,008, 106,013, dated November 14, 2014
NPL464	University of Western Australia v. Academisch Ziekenhuis Leiden, Order to Show Cause- 37 CFR§ 41.104(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-3 (Doc 193).
NPL465	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecclaration, Patent Interference No. 106,008, 2 pages, dated September 23, 2014 (Doc 19)
NPL466	University of Western Australia v. Academisch Ziekenhuis Leiden, Second Declaration of Matthew J. A. Wood, M.D., D. PHIL., Patent Interference Nos. 106,007 and 106,008, 78 pages, dated February 17, 2015 (Exhibit Number 2116 filed in interferences 106,007 and 106,008, on February 17, 2015.
NPL467	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Initial Settlement Discussions, 3 pages, Patent Interference No. 106,013, (Doc 136), dated December 30, 2014.
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NPL471	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Response to Order to Show Cause, filed in Patent Interference No. 106,013, July 20, 2015, pages 1-28 (Doc 194).

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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NPL473	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-10 (Doc 464).
NPL474	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106007, April 3, 2015, pages 1-10 (Doc 431).
NPL475	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106008, April 3, 2015, pages 1-10 (Doc 439).
NPL476	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106013, April 3, 2015, pages 1-10 (Doc 153).
NPL477	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List As of October 29, 2015, filed in Patent Interference No. 106,013, October 29, 2015, pages 1-10 (Doc 199).

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Application Number # 33384	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL478	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,007, April 10, 2015, pages 1-21 (Doc 455).
NPL479	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,008, April 10, 2015, pages 1-21 (Doc 463).
NPL480	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 38 pages, Patent Interference No. 106,007, (Doc 393), dated February 17, 2015
NPL481	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 39 pages, Patent Interference No. 106,008, (Doc 402), dated February 17, 2015
NPL482	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 31 pages, Patent Interference No. 106,008, (Doc 403), dated February 17, 2015
NPL483	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 37 pages, Patent Interference No. 106,007, (Doc 394), dated February 17, 2015
NPL484	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,007, (Doc 395), dated February 17, 2015
NPL485	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,008, (Doc 404), dated February 17, 2015
NPL486	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 104 and 105), 36 pages, Patent Interference No. 106,007, (Doc 397), dated February 17, 2015
NPL487	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 30 and 31), 36 pages, Patent Interference No. 106,008, (Doc 405), dated February 17, 2015
NPL488	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in interference 106007, pages 1-28 (Doc 428).

Application Number # 33385	16/112,371
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL489	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106008, pages 1-28, (Doc 436).
NPL490	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to Maintain the Interference) filed April 3, 2015 in Interference 106013, pages 1-17 (Doc 152).
NPL491	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106007, pages 1-22 (Doc 429)
NPL492	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106008, pages 1-22 (Doc 437).
NPL493	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (for Judgment under 35 U.S.C. §135(b)) filed April 3, 2015 in Interference 106008, pages 1-19 (Doc 438).
NPL494	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (to Institute an Interference) filed April 3, 2015 in Interference 106007, pages 1-17 (Doc 430).
NPL495	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,007, May 12, 2015, pages 1-13 (Doc 467).
NPL496	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,008, May 12, 2015, pages 1-13 (Doc 475).
NPL497	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-4 (Doc 457).
NPL498	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-4 (Doc 465).
NPL499	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 190).

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL500	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005. (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL501	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL502	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL503	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL504	Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL505	REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)
NPL506	REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)
NPL507	Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012, 2 pages, (Exhibit Number 1072 filed in Interferences 106008, 106007 on December 23, 2014)
NPL508	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL509	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).
NPL510	Reply to EPO Communication dated October 23, 2014 in European Application Serial No. 12198485, (University of Western Australia Exhibit 2147, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-8).

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL511	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 134)
NPL512	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 7 pages, Patent Interference Nos. 106,008, dated December 12, 2014 (Doc 221)
NPL513	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 8 pages, Patent Interference No. 106,007, dated December 12, 2014 (Doc 217)
NPL514	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,007, 7 pages, dated September 10, 2014 (Doc 17)
NPL515	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,008, 6 pages, dated September 10, 2014 (Doc 16)
NPL516	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Miscellaneous Motion 1 (for authorization to file terminal disclaimer), 5 pages, Patent Interference No. 106,008, dated October 17, 2014 (Doc 22)
NPL517	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 U.S.C., section 112(a)), 40 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 210)
NPL518	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 § 112(a)) Patent Interference No. 106,008 (Doc 213), 38 Pages, on November 18, 2014
NPL519	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (To Maintain Interference between UWA US Patent No. 8,486,907 and AZL USSN 14/198,992), 45 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 133)
NPL520	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 32 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 214)
NPL521	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 34 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 211)

Application Number # 33388	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL522	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 (For judgment that Claims 11-12, 14-15, and 17-29 of Application No. 13/550,210 are barred under 35 U.S.C. section 135(b)), 25 Pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 215)
NPL523	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 Requesting an additional interference between UWA U.S. Patent No. 8,455,636 and AZL USSN 14/248,279, 36 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 212)
NPL524	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)
NPL525	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 218)
NPL526	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, July 2, 2015, pages 1-16 (Doc 469).
NPL527	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, September 2, 2015, pages 1-18 (Doc 470).

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EXAMINER SIGNATURE

Examiner Signature	/KIMBERLY CHONG/ (12/20/2018)	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Application Number	16/112,371 # 33389
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL528	US Application No. 14/248,279, 29 pages; excerpts of prosecution history including: Amendment under 37 CFR 1.312 dated September 19, 2014; Amendment in Response to Final Office Action dated August 7, 2014; Declaration under 37 CFR 1.132 dated May 26, 2014; Declaration under 37 CFR 1.132 dated May 27, 2014; Response dated June 3, 2014 (Exhibit Number 2057 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL529	US Application No. 13/550,210, 27 pages; excerpts of prosecution history including: Response and Amendment dated May 12, 2014; Response to Non-Final Office Action dated January 21, 2014; Second Preliminary Amendment dated January 3, 2013 (Exhibit Number 2055 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL530	US claim amendments for Application No. 13/550,210, 3 pages, dated May 12, 2014 (Exhibit Number 2078 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL531	US Claims for Application No. 12/976,381, 1 page, dated December 22, 2010 (Exhibit Number 2065 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL532	US Declaration of Richard K. Bestwick, for Application No. 11/570,691, 5 pages, dated June 15, 2010 (Exhibit Number 1044 filed in interferences 106008, 106007 on November 18, 2014)
NPL533	US E-mail from Patent Trial and Appeal Board to Danny Huntington, 2 pages, dated October 9, 2014 (Exhibit Number 2002 filed in interferences 106008 on October 17, 2014)
NPL534	US Non-Final Office Action for Application No. 11/570,691, 16 pages, dated March 15, 2010 (Exhibit Number 1042 filed in interferences 106008, 106007 on November 18, 2014)
NPL535	US Office Action for Application No. 13/271,080, 25 pages, dated July 30, 2012 (Exhibit Number 1048 filed in interferences 106008, 106007 on November 18, 2014)
NPL536	US Office Action for Application No. 13/550,210, 12 pages, dated September 27, 2013 (Exhibit Number 2080 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL537	US Office Action for Application No. 13/902,376, 7 pages, dated January 7, 2014 (Exhibit Number 1045 filed in interferences 106008, 106007 on November 18, 2014)
NPL538	US Patent Application No. 12/198,007 as-filed, 64 pages, dated August 25, 2008 (Exhibit Number 2092 filed in interferences 106008, 106013, and 106007 on November 18, 2014)

Application Number # 33390	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL539	US Preliminary Amendment and application as-filed for Application No. 12/976,381, 64 pages, dated December 22, 2010 (Exhibit No. 2089 filed in Interferences 106007, 106008, and 106013 on November 18, 2014)
NPL540	US Preliminary Amendment for Application No. 11/233,495, 10 pages, dated September 21, 2005 (Exhibit Number 2069 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL541	US Preliminary Remarks for Application No. 14/198,992, 1 page, dated March 6, 2014 (Exhibit Number 2097 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
NPL542	US Proposed Terminal Disclaimer for Application No. 12/860,078, 2 pages, dated October 17, 2014 (Exhibit Number 2001 filed in interference 106008 on October 17, 2014)
NPL543	US Remarks for Application No. 14/248,279, 2 pages, dated August 27, 2014 (Exhibit Number 2110 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL544	US Response and amendments for Application No. 13/550,210, 12 pages, dated January 21, 2014 (Exhibit Number 2063 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL545	US Revised Figure 4H, US Application No. 13/271,080, 1 page (Exhibit Number 1050 filed in interferences 106008, 106007 on November 18, 2014)
NPL546	US Terminal Disclaimer for Application No. 14/198,992, 1 page, dated July 15, 2014 (Exhibit Number 2096 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL547	US Terminal Disclaimer for Application No. 14/248,279, 1 page, dated August 7, 2014 (Exhibit Number 2109 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL548	US Track One Request, Application as-filed, and Application Data Sheet for Application No. 14/248,279, 68 pages, dated April 8, 2014 (Exhibit Number 2108 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL549	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 11/570,691, 102 pages, dated December 15, 2006 (Exhibit Number 2103 filed in interferences 106008, 106013, 106007 on November 18, 2014)

Application Number	16/112,371 # 33391
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL550	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/270,992, 101 pages, dated October 11, 2011 (Exhibit Number 2098 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL551	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/271,080, 115 pages, dated October 11, 2011 (Exhibit Number 2111 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL552	US Updated Filing Receipt for Application No. 13/550,210, 3 pages, dated December 11, 2012 (Exhibit Number 2044 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL553	USPTO "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving...Natural Products" ("the March Guidance"), 19 pages, (Exhibit Number 2118 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL554	USPTO Written Description Training Materials, Revised March 25, 2008, Example 12, 6 pages, (Exhibit Number 1068 filed in interferences 106008, 106007 on December 23, 2014)
NPL555	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 1, 2014 (Paper 12), 8 pages, (Exhibit Number 2126 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL556	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 7, 2014 (Paper 12), 8 pages, (Exhibit Number 2127 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL557	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,007 (PN210), 40 Pages, Exhibit Number 1005 filed in Interference 106,013 on February 17, 2015.
NPL558	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,008 (Doc 213), Pages 38, Exhibit Number 1004 filed in Interference 106,013 on February 17, 2015.
NPL559	JWA submission of teleconference transcript , 28 pages, dated December 12, 2014 (Exhibit Number 2114 filed in interferences 106008 and 106007 on December 12, 2014)
NPL560	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).

Application Number	16/112,371
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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL561	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in Interferences 106008, 106007 on December 23, 2014)
NPL562	van Deutekom et al., "Local Dystrophin Restoration with Antisense Oligonucleotide PRO051," N. Engl. J. Med., Vol. 357, No. 26, pp. 2677-2686 (December, 2007), Exhibit Number 1213 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL563	VAN DEUTEKOM, Judith C. T. et al., "Advances in Duchenne Muscular Dystrophy Gene Therapy," Nature Reviews Genetics, Vol. 4(10):774-783 (2003)
NPL564	van Ommen 2002 PCT (WO 02/24906 A1), 43 pages,(Exhibit Number 1071 filed in interferences 106008, 106007 on December 23, 2014)
NPL565	van Putten M, et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages
NPL566	Van Vliet, Laura et al., "Assessment of the Feasibility of Exon 45-55 Multiexon Skipping for Duchenne Muscular Dystrophy", BMC Medical Genetics, Vol.9(1):105 (2008)
NPL567	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in interferences 106008, 106007 on November 18, 2014)
NPL568	Vikase Corp. v. Am. Nat'l. Can Co., No. 93-7651, 1996 WL 377054 (N.D. Ill. July 1, 1996), 3 pages (Exhibit Number 2152 filed in interference 106013 on October 29, 2015)
NPL569	VOIT, Thomas et al., "Safety and efficacy of drisapersen for the treatment of Duchenne muscular dystrophy (DEMAND 1): an exploratory, randomised, placebo-controlled phase 2 study," Lancet Neurol., Vol. 13:987-996 (2014) (Exhibit Number 2037 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL570	VOLLOCH, Vladimir et al., "Inhibition of Pre-mRNA Splicing by Antisense RNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons," Biochemical and Biophysical Research Communications, Vol. 179 (3):1593-1599 (1991)
NPL571	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.

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First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
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**INFORMATION DISCLOSURE
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NPL572	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, July 2, 2015, pages 1-16 (Doc 477).
NPL573	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, September 2, 2015, pages 1-18 (Doc 478).
NPL574	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 11)
NPL575	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,008, 5 pages, dated August 7, 2014 (Doc 11)
NPL576	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 14, 2014 (Doc 6)
NPL577	JS 7,960,541 (Wilton et al.), Pages 84, Exhibit Number 1002 filed in interferences 106,007 and 106,008 on November 18, 2014.
NPL578	JS 8,450,474 (Wilton et al.), Pages 95, Exhibit Number 1087 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL579	JS 8,455,634 (Wilton et al.) Pages 96, Exhibit Number 1088 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL580	JS 8,455,635 (Wilton et al.), Pages 96, Exhibit Number 1089 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL581	JS 8,455,636 (Wilton et al.), Pages 92, Exhibit Number 1003 filed in interferences 106,007 and 106,008 on November 18, 2014.
NPL582	JS 8,476,423 (Wilton et al.), Pages 95, Exhibit Number 1111 filed in interferences 106,007 and 106,008 on February 13, 2015.

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Examiner Name	K. Chong	
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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL583	JS 8,501,703 (Bennett et al.), Pages 16, Exhibit Number 1090 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL584	JS 8,501,704 (Mourich et al.), Pages 39, Exhibit Number 1091 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL585	JS 8,524,676 (Stein et al.), Pages 28, Exhibit Number 1092 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL586	JS 8,524,880 (Wilton et al.), Pages 89, Exhibit Number 1093 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL587	JS 8,536,147 (Weller et al.), Pages 95, Exhibit Number 1094 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL588	JS 8,592,386 (Mourich et al.), Pages 46, Exhibit Number 1095 filed in interferences 106,007 and 106,008 on February 13, 2015.
NPL589	JS 8,618,270 (Iversen et al.), Pages 28, Exhibit Number 1096 filed in interferences 106,007 and 106,008 on February 13, 2015.
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NPL607	US Amendment for Application No. 11/233,495, 19 pages, dated September 16, 2009 (Exhibit Number 2072 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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NPL611	US Amendment for Application No. 13/902,376, 36 pages, dated March 21, 2014 (Exhibit Number 1046 filed in interferences 106008, 106007 on November 18, 2014)
NPL612	US Amendment in Response to Advisory Action for Application No. 11/233,495, 23 pages, dated March 14, 2011 (Exhibit Number 2074 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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NPL615	US Applicant-Initiated Interview Summary and Notice of Allowance for Application No. 13/550,210, 9 pages dated May 19, 2014 (Exhibit Number 2076 filed in interferences 106008, 106013, 106007 on November 18, 2014)

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NPL617	US Application as-filed for application No. 14/198,992, 52 pages, dated March 6, 2014 (Exhibit Number 2086 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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	Art Unit	1635
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	Attorney Docket Number	4140.01500B0

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NPL682	AON PS1961 Mass Spectrometry Data, Pages 5, Exhibit Number 1149 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL683	AON PS1961 UPLC Data, Pages 2, Exhibit Number 1160 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL684	AON PS1962 Mass Spectrometry Data, Pages 7, Exhibit Number 1150 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL685	AON PS1962 UPLC Data, Pages 2, Exhibit Number 1161 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL686	AON PS1963 Mass Spectrometry Data, Pages 10, Exhibit Number 1151 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL687	AON PS1963 UPLC Data, Pages 2, Exhibit Number 1162 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL688	AON PS1964 Mass Spectrometry Data, Pages 13, Exhibit Number 1152 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL689	AON PS1964 UPLC Data, Pages 2, Exhibit Number 1163 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL690	AON PS1965 Mass Spectrometry Data, Pages 9, Exhibit Number 1153 filed in Interferences 106,007 and 106,008 on February 16, 2015.

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL691

AON PS1965 UPLC Data, Pages 2, Exhibit Number 1164 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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Application Number # 33430	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL692	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Rehearing, filed in Patent Interference No. 106,013, October 29, 2015, pages 1-20 (Doc 198).
NPL693	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,007, (Doc 415), dated March 10, 2015.
NPL694	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,013, (Doc 150), dated March 10, 2015.
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NPL696	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,007, (Doc No. 398) dated February 17, 2015.
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Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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NPL703	Wang et al., "In Vitro evaluation of novel antisense oligonucleotides is predictive of in vivo exon skipping activity for Duchenne muscular dystrophy," J. Gene Medicine, Vol. 12, pp. 354-364 (March, 2010), Exhibit Number 1115 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL704	WANG, Chen-Yen et al., "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse," Proc. Natl. Acad. Sci. USA, Vol. 84:7851-7855 (1987)
NPL705	WATAKABE, Akiya et al., "The role of exon sequences in splice site selection," Genes & Development, Vol. 7:407-418 (1993)
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				Application Number	16/112,453	
				Filing Date	August 24, 2018	
				First Named Inventor	Stephen Donald WILTON	
				Art Unit	1635	
				Examiner Name	Chong, Kimberly	
Sheet	1	of	1	Attorney Docket Number		4140.01500B0

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	NPL709	Office Action mailed July 12, 2018, in United States Patent Application No. 15/645,842, Wilton et al., filed July 10, 2017, 19 pages	
	NPL710	Office Action mailed July 31, 2018, in United States Patent Application No. 15/655,646, Wilton et al., filed July 20, 2017, 15 pages	
	NPL711	Office Action mailed September 7, 2018, in United States Patent Application No. 15/673,019, Wilton et al., filed August 9, 2017, 9 pages	
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33433

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	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
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Application Number	16/112,371 # 33434
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL1	Extended European Search Report, EP 17159328.8, dated September 5, 2017, 10 pages.		
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	Filing Date	August 24, 2018
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	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	US1	9506058		2016-11-29	Kaye	
	US2	9605262		2017-03-28	Wilton et al.	

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	US3	20130190390	A1	2013-07-25	SAZANI et al.	
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	FP1	2013/142087	WO	A1	2013-09-26	Sarepta Therapeutics, Inc		

Application Number 16/112,371
 # 33436
 Filing Date August 24, 2018
 First Named Inventor WILTON, Stephen
 Art Unit 1635
 Examiner Name K. Chong
 Attorney Docket Number 4140.01500B0

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FP2	2014/172669	WO	A1	2014-10-23	Research Institute at Nationwide Children's Hosp.		
FP3	2017/059131	WO	A1	2017-04-06	Sarepta Therapeutics, Inc		

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	NPL2	GenBank AF213437.1 Dated January 17, 2002	
	NPL3	International Search Report and Written Opinion, PCT/US2016/054534, dated January 17, 2017, 13 pages.	
	NPL4	KOLE et al., "Exon skipping therapy for Duchenne muscular dystrophy," Advanced Drug Delivery Reviews, vol. 37:104-107 (2015).	
	NPL5	WHO Drug Information, International Nonproprietary Names for Pharmaceutical Substances (INN), Proposed INN: List 115, "CASIMERSEN," vol. 30(2): 3 pages (2016)	
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	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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	US5	8436163		2013-05-07	Iversen et al.	
	US6	9416361		2016-08-16	Iversen et al.	

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	US7	20040266720	A1	2004-12-30	Iversen et al.	
	US8	20120053228	A1	2012-03-01	Iversen et al.	
	US9	20140045916	A1	2014-02-13	Iversen et al.	
	US10	20150232839	A1	2015-08-20	Iversen et al.	

Application Number **# 33438** 16/112,371
 Filing Date **August 24, 2018**
 First Named Inventor **WILTON, Stephen**
 Art Unit **1635**
 Examiner Name **K. Chong**
 Attorney Docket Number **4140.01500B0**

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	US11	20160298111	A1	2016-10-13	Bestwick et al.	
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	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
	Attorney Docket Number	4140.01500B0

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	US12	9453225		2016-09-27	Sazani et al.	
	US13	9447417		2016-09-20	Sazani et al.	
	US14	9447416		2016-09-20	Sazani et al.	
	US15	9447415		2016-09-20	Wilton et al.	
	US16	9441229		2016-09-13	Wilton et al.	
	US17	9434948		2016-09-06	Sazani et al.	
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 Art Unit 1635
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 Attorney Docket Number 4140.01500B0

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	NPL7	Errata to the Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Errata Document, NDA 206488, 5 pages.	
	NPL8	Extended European Search Report, EP 15190341.6, dated April 28, 2016, 9 pages.	
	NPL9	FDA Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen, NDA 206488, 115 pages	
	NPL10	FDA News Release, "FDA grants accelerated approval to first drug for Duchenne muscular dystrophy," September 19, 2016, 3 pages.	

Application Number	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL11	Jett Foundation Presentation by McSherry, C. "Patient and Caregiver-Reported Outcomes of Patients in Clinical Trials of Eteplirsen for Treatment of Duchenne" at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 17 pages.
NPL12	Letter from the FDA to Sarepta Therapeutics, Inc., Re: ACCELERATED APPROVAL for the use of Exondys 51 (eteplirsen), FDA Reference ID: 3987286, dated September 19, 2016, 11 pages.
NPL13	Letter to the U.S. Food and Drug Administration, (Dr. Billy Dunn, M.D. Director Division of Neurology Products, Office of Drug Evaluation 1, Center for Drug Evaluation and Research), for The Peripheral and Central Nervous System Advisory Committee Meeting (AdComm) supporting approval of eteplirsen, dated February 24, 2016, 4 pages.
NPL14	Letter to the U.S. Food and Drug Administration, (Dr. Janet Woodcock, M.D. Director, CDER), from The Congress of The United States regarding Duchenne muscular dystrophy, dated February 17, 2016, 7 pages.
NPL15	Prescribing Information for EXONDYS 51 (eteplirsen) Injection, dated 09/2016, 10 pages
NPL16	Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Briefing Document, NDA 206488, 186 pages.
NPL17	Sarepta Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 133 pages
NPL18	Sarepta Press Release, Sarepta Issues Statement on Advisory Committee Outcome for Use of Eteplirsen in the Treatment of Duchenne Muscular Dystrophy, April 25, 2016, 2 pages
NPL19	Sarepta Therapeutics, Inc. News Release, "Sarepta Therapeutics Announces FDA Accelerated Approval of EXONDYS 51™ (eteplirsen) injection, an Exon Skipping Therapy to Treat Duchenne Muscular Dystrophy (DMD) Patients Amenable to Skipping Exon 51," September 19, 2016, 2 pages.
NPL20	U.S. Food and Drug Administration Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 178 pages.
NPL21	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 C.F.R. § 41.125(a), filed in Patent Interference No. 106008, September 20, 2016, pages 1-20 (Doc 480)

Application Number # 33442	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

NPL22	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a) (Substitute), filed in Patent Interference No. 106007, May 12, 2016, pages 1-53 (Doc 476)
NPL23	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 C.F.R. § 41.127 filed in Patent Interference No. 106008, September 20, 2016, pages 1-3 (Doc 481)
NPL24	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 CFR § 41.127, filed in Patent Interference No. 106007, April 29, 2016, pages 1-3, (Doc 474)
NPL25	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecaration - 37 CFR 41.203(c), filed in Patent Interference No. 106007, April 29, 2016, pages 1-2, (Doc 473)
NPL26	University of Western Australia v. Academisch Ziekenhuis Leiden, Withdrawal and Reissue of Decision on Motions, filed in Patent Interference No. 106007, May 12, 2016, pages 1-2 (Doc 475)
NPL27	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a), filed in Patent Interference No. 106007, April 29, 2016, pages 1-53, (Doc 472)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/112,371
	Filing Date	August 24, 2018
	First Named Inventor	WILTON, Stephen
	Art Unit	1635
	Examiner Name	K. Chong
Attorney Docket Number		4140.01500B0

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	FP6	2002-325582	JP	A	2002-11-12	MATSUO, MASAFUMI, ET AL.		

Application Number	16/112,371
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Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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FP10	2010-268815	JP	A	2010-12-02	MATSUO MASAFUMI
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FP13	2014-054250	JP	A	2014-03-27	NIPPON SHINYAKU CO LTD.
FP14	2014-111638	JP	A	2014-06-19	ACADEMISCH, ZIEKENHUIS LEIDEN
FP15	2014-138589	JP	A	2014-07-31	ACADEMISCH, ZIEKENHUIS LEIDEN
FP16	4777777	JP	B2	2011-09-21	KOBE UNIVERSITY
FP17	4846965	JP	B2	2011-12-28	ACADEMISCH ZIEKENHUIS LEIDEN

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FP21	00/44897	WO	A1	2000-08-03	AVI Biopharma, Inc.		
FP22	00/78341	WO	A1	2000-12-28	Murdoch Childrens Research Institute		
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FP24	01/72765	WO	A1	2001-10-04	SIS Pharmaceuticals, Inc.		
FP25	01/83503	WO	A2	2001-11-08	Hybridon, Inc		
FP26	01/83740	WO	A2	2001-11-08	AVI Biopharma, Inc.		
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Application Number 16/112,371
 # 33448
 Filing Date August 24, 2018
 First Named Inventor WILTON, Stephen
 Art Unit 1635
 Examiner Name K. Chong
 Attorney Docket Number 4140.01500B0

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FP51	2010/136417	WO	A1	2010-12-02	Universita Degli Studi di Roma "La Sapienza"	<input type="checkbox"/>
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FP53	2011/024077	WO	A2	2011-03-03	Inserm, Institut National de la Sante et de la Rec	<input type="checkbox"/>

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	NPL28	AON PS1966 Mass Spectrometry Data, Pages 8, Exhibit Number 1154 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL29	AON PS1966 UPLC Data, Pages 2, Exhibit Number 1165 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL30	AON PS1967 Mass Spectrometry Data, Pages 7, Exhibit Number 1155 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL31	AON PS1967 UPLC Data, Pages 2, Exhibit Number 1166 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL32	AON PS229 (h53AON1) HPLC Chromatograph Pages 2, Exhibit Number 1140 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL33	AON PS229 (h53AON1) HPLC Method Report, Pages 3, Exhibit Number 1139 filed in Interferences 106,007 and 106,008 on February 16, 2015.	

Application Number # 33449	16/112,371
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL34	AON PS229 (h53AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1142 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL35	AON PS229 (h53AON1) Synthesis Laboratory Notebook Entry, Pages 1, Exhibit Number 1137 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL36	AON PS229L (h53AON229L) Certificate of Analysis, Pages 1, Exhibit Number 1129 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL37	AON PS43 (h51AON1) Certificate of Analysis, Pages 1, Exhibit Number 1134 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL38	AON PS43 (h51AON1) HPLC Chromatogram, Pages 1, Exhibit Number 1131 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL39	AON PS43 (h51AON1) HPLC Method Report, Pages 4, Exhibit Number 1130 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL40	AON PS43 (h51AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1135 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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NPL44	Arechavala-Gomez V, et al., "Immunohistological intensity measurements as a tool to assess sarcolemma-associated protein expression," Neuropathol Appl Neurobiol 2010;36: 265-74.

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Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL51	AZL's PCT/NL03/00214 (the as-filed AZL PCT Application) Exhibit No. 1006, filed in Interference No. 106,007, 64 pages, December 23, 2014
NPL52	AZL's U.S. Patent Application No. 14/295,311 and claims, as-filed June 3, 2014 ("the '311 Application") (Exhibit Number 1077 filed in interferences 106008, 106007 on December 23, 2014)
NPL53	Azofeifa J, et al., "X-chromosome methylation in manifesting and healthy carriers of dystrophinopathies: concordance of activation ratios among first degree female relatives and skewed inactivation as cause of the affected phenotypes," Hum Genet 1995;96:167-176.
NPL54	BEAUCAGE, S.L. et al., "Deoxynucleoside Phosphoramidites - A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters, Vol. 22(20):1859-1862 (1981)
NPL55	BELLARE, Priya et al., "A role for ubiquitin in the spliceosome assembly pathway," Nature Structural & Molecular Biology, Vol. 15(5):444-451 (2008) (Exhibit Number 1057 filed in interferences 106008, 106007 on November 18, 2014)

Application Number	16/112,371 # 33451
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

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NPL57	BENNETT, C. Frank et al., "RNA Targeting Therapeutics: Molecular Mechanisms of Antisense Oligonucleotides as a Therapeutic Platform," Annu. Rev. Pharmacol. Toxicol., Vol. 50:259-293 (2010) (Exhibit Number 1025 filed in interferences 106008, 106007 on November 18, 2014)
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NPL60	BRAASCH, Dwaine A. et al., "Locked nucleic acid (LNA): fine-tuning the recognition of DNA and RNA," Chemistry & Biology, Vol. 8:1-7 (2001) (Exhibit Number 2009 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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NPL63	Brooke MH, et al., "Clinical investigation in Duchenne dystrophy: 2. Determination of the "power" of therapeutic trials based on the natural history," Muscle Nerve. 1983;6:91-103.
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Examiner Name	K. Chong
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NPL68	CANONICO, A.E. et al., "Expression of a CMV Promoter Drive Human alpha-1 Antitrypsin Gene in Cultured Lung Endothelial Cells and in the Lungs of Rabbits," Clinical Research, Vol. 39(2):219A (1991)
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NPL70	Claim Chart 11/233,495, Pages 57, Exhibit Number 1216 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL71	Claim Chart 13/550,210, Pages 45, Exhibit Number 1217 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL72	Claim Chart, US 7,807,816, 14 pages (Exhibit Number 1063 filed in interferences 106008, 106007 on November 18, 2014)
NPL73	Claim Chart, US 7,960,541, 17 pages (Exhibit Number 1064 filed in interferences 106008, 106007 on November 18, 2014)
NPL74	Claim Chart, US 8,455,636, 32 pages (Exhibit Number 1062 filed in interferences 106008, 106007 on November 18, 2014)
NPL75	Claim Comparison Chart - Claims 11 and 29 in 13/550,210, Pages 1, Exhibit Number 1226 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL76	Claim Comparison Chart 13/550,210 vs 11/233,495, Pages 12, Exhibit Number 1218 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL77	Claim Comparison Chart 13/550,210 vs 12/198,007, Pages 1, Exhibit Number 1219 filed in Interferences 106,007 and 106,008 on February 17, 2015.

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	FP56	2011/143008	WO	A1	2011-11-17	The Charlotte-Mecklenburg Hospital Authority D/B/A		

Application Number	16/112,371
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Application Number 16/112,371
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 First Named Inventor WILTON, Stephen
 Art Unit 1635
 Examiner Name K. Chong
 Attorney Docket Number 4140.01500B0

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	NPL78	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in Interferences 106008, 106013, 106007 on November 18, 2014)	
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	NPL82	Confirmation of Dystrophin Exon 52 Deletion in Cell Line R1809 Laboratory; Notebook Entry, Pages 3, Exhibit Number 1168 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	NPL83	Confirmatory Study of Eteplirsen in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy, Clinical Trials.gov, Clinical Trial Identifier NCT02255552, October 1, 2014, 3 pages	
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First Named Inventor	WILTON, Stephen
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Art Unit	1635
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First Named Inventor	WILTON, Stephen
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First Named Inventor	WILTON, Stephen
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NPL178	Excerpts from Prosecution History of Application No. 13/741,150: Notice of Allowance dated March 16, 2015; List of References cited by Applicant and Considered by Examiner; Notice of Allowance and Fees due dated September 18, 2014; Amendment in Response to Non-Final Office Action dated July 11, 2014, (Academisch Ziekenhuis Leiden Exhibit 1229, filed April 3, 2015 in Interference 106007 and 106008, pages 1-133).
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(Not for submission under 37 CFR 1.99)

NPL189	Federal Register, Vol. 69, No. 155, pp. 49960-50020 dated August 12, 2004 (62 pages), Exhibit Number 1220 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL190	File Excerpt from AZL U.S. Patent Application 11/233,495: Amendment After Non-Final Office Action, as-filed November 1, 2010 (Exhibit Number 1085 filed in interferences 106008, 106007 on December 23, 2014)
NPL191	File Excerpt from AZL U.S. Patent Application 11/233,495: Claims examined in Non-Final Office Action, dated December 1, 2008 (Exhibit Number 1079 filed in interferences 106008, 106007 on December 23, 2014)
NPL192	File Excerpt from AZL U.S. Patent Application 11/233,495: Final Office Action dated August 31, 2010 (Exhibit Number 1086 filed in interferences 106008, 106007 on December 23, 2014)
NPL193	File Excerpt from U.S. Patent Application 11/233,495: Non-Final Office Action dated December 1, 2008 and Final Office Action dated June 25, 2009 (Exhibit Number 1078 filed in interferences 106008, 106007 on December 23, 2014)
NPL194	File Excerpt from U.S. Patent Application No. 12/198,007: AZL's Preliminary Amendment and Response, as-filed November 7, 2008 (Exhibit Number 1075 filed in interferences 106008, 106007 on December 23, 2014)
NPL195	File Excerpt from U.S. Patent Application No. 12/976,381: AZL's First Preliminary Amendment, as-filed December 22, 2010 (Exhibit Number 1076 filed in interferences 106008, 106007 on December 23, 2014)
NPL196	File Excerpts from Prosecution History of U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907"), Pages 122, Exhibit Number 1006 filed in Interference 106,013 on February 17, 2015.
NPL197	File Excerpts from U.S. Patent Application No. 11/233,495: Response to Non-Final Office Action, as filed July 26, 2011 (14 pages), Exhibit Number 1222 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL198	File Excerpts from U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907"): NFOA, dated 7/30/2012; Applicant-Initiated Interview Summary, dated 11/8/2012; Amendment, as filed January 30, 2013; NOA, dated 4/4/2013, Exhibit Number 1118 (122 pages) filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL199	Flanagan, W. Michael, et al., "A cytosine analog that confers enhanced potency to antisense oligonucleotides," Proc. Nat'l Acad. Sci. USA, Vol. 96, pp. 3513-3518 (March, 1999), Exhibit Number 1211 filed in Interferences 106,007 and 106,008 on February 17, 2015.

Application Number	16/112,371 # 33468
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL200	FLANIGAN, Kevin M. et al., "Pharmacokinetics and safety of single doses of drisapersen in non-ambulant subjects with Duchenne muscular dystrophy: Results of a double-blind randomized clinical trial," Neuromuscular Disorders, Vol. 24:16-24 (2014) (Exhibit Number 2038 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL201	Flanigan, Kevin M., et al. (2003) "Rapid Direct Sequence Analysis of the Dystrophin Gene," Am. J. Hum. Genet. 72:931-939, dated February 17, 2015 (Exhibit Number 2120 filed in interferences 106,007 and 106,008 on February 17, 2015.
NPL202	Fletcher S., et al, "Morpholino oligomer-mediated exon skipping averts the onset of dystrophic pathology in the mdx mouse. Mol Ther 2007;15:1587-1592.
NPL203	FLETCHER, Sue et al., "Dystrophin Isoform Induction in Vivo by Antisense-mediated Alternative Splicing," Molecular Therapy, Vol. 18(6):1218-1223 (2010)
NPL204	FLETCHER, Sue et al., "Targeted Exon Skipping to Address 'Leaky' Mutations in the Dystrophin Gene," Molecular Therapy-Nucleic Acids, Vol. 1, e48, doi:10.1038/mtna.2012.40, 11 pages (2012)
NPL205	FLETCHER, Susan et al., "Dystrophin expression in the mdx mouse after localised and systemic administration of a morpholino antisense oligonucleotide," J. Gene Med., Vol. 8:207-216 (2006)
NPL206	FLETCHER, Susan et al., "Gene therapy and molecular approaches to the treatment of hereditary muscular disorders," Curr. Opin. Neurol., Vol. 13:553-560 (2000)
NPL207	FOSTER, Helen et al., "Genetic Therapeutic Approaches for Duchenne Muscular Dystrophy," Human Gene Therapy, Vol. 23:676-687 (2012)
NPL208	Fourth Declaration of Erik Sontheimer, Ph.D. (Pursuant to Bd.R. 41.155(b)(2) and SO 155.1.3 and 155.1.4), dated March 9, 2015, (University of Western Australia Exhibit 2138, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
NPL209	FRAGALL, Clayton T. et al., "Mismatched single stranded antisense oligonucleotides can induce efficient dystrophin splice switching," BMC Medical Genetics, Vol. 12:141, 8 pages (2011) (Exhibit Number 2019 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL210	FRALEY, Robert et al., "New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids," Trends Biochem., Vol. 6:77-80 (1981)

Application Number	16/112,371 # 33469
Filing Date	August 24, 2018
First Named Inventor	WILTON, Stephen
Art Unit	1635
Examiner Name	K. Chong
Attorney Docket Number	4140.01500B0

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

NPL211	FRAZIER, Kendall S. et al., "Species-specific Inflammatory Responses as a Primary Component for the Development of Glomerular Lesions in Mice and Monkeys Following Chronic Administration of a Second-generation Antisense Oligonucleotide," Toxicologica Pathology, 13 pages (2013)
NPL212	FRIEDMANN, Theodore, "Progress Toward Human Gene Therapy," Science, Vol. 244(4910):1275-1281 (1989)
NPL213	GEBSKI, Bianca L. et al., "Morpholino antisense oligonucleotide induced dystrophin exon 23 skipping in mdx mouse muscle," Human Molecular Genetics, Vol. 12(15):1801-1811 (2003)
NPL214	Generic Method for Average Mass Determination Using LC-UV-MS in the Negative Mode, Pages 15, Exhibit Number 1145 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL215	Generic UPLC Purity Method for Oligonucleotides (19- to 25-mers), Pages 18, Exhibit Number 1156 filed in Interferences 106,007 and 106,008 on February 16, 2015.
NPL216	GENNARO, Alfonso R., (ed.), Remington's Pharmaceutical Sciences, 18th Edition, Mack Publishing, Co., Easton PA, 2020 pages (1990)
NPL217	GILES, Richard V. et al., "Antisense Morpholino Oligonucleotide Analog Induces Missplicing of C-myc mRNA," Antisense & Nucleic Acid Drug Development, Vol. 9:213-220 (1999)
NPL218	GlaxoSmithKline Press Release, Issued in London, UK, dated June 27, 2013 (5 pages), Exhibit Number 1202 filed in Interferences 106,007 and 106,008 on February 17, 2015.
NPL219	GlaxoSmithKline, "GSK and Prosensa announce start of Phase III study of investigational Duchenne Muscular Dystrophy medication," press release, 6 pages, dated January 19, 2011 (Exhibit Number 2060 filed in interferences 106008, 106013, 106007 on November 18, 2014)
NPL220	GlaxoSmithKline, "Prosensa regains rights to drisapersen from GSK and retains rights to all other programmes for the treatment of Duchenne muscular dystrophy (DMD), press release, 4 pages, dated January 13, 2014 (Exhibit 2040 in interferences 106007, 106008, and 106013 on November 18, 2014).
NPL221	GOEMANS, Nathalie M. et al., "Systemic Administration of PRO051 in Duchenne's Muscular Dystrophy," The New England Journal of Medicine, Vol. 364:1513-1522 (2011) (Exhibit Number 2036 filed in interferences 106008, 106013, 106007 on November 18, 2014)

PTO/AIA/01 (06-12)

Approved for use through 01/31/2014. OMB 0651-0032

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention****ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING
AND METHODS OF USE THEREOF**

As the below named inventor, I hereby declare that:

This declaration ☐ The attached application, or
is directed to:☒ United States application or PCT international application number 13/741,150
filed on 01/14/2013

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001
by fine or imprisonment of not more than five (5) years, or both.**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Stephen Donald WILTONDate (Optional): 26/03/13Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

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This declaration ☐ The attached application, or
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LEGAL NAME OF INVENTOR

Inventor: Sue FLETCHER

Date (Optional): 26/03/2013

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

**Title of
Invention**

**ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING
AND METHODS OF USE THEREOF**

As the below named inventor, I hereby declare that:

This declaration ☐ The attached application, or
is directed to:

☒ United States application or PCT international application number 13/741,150
filed on 01/14/2013

The above-identified application was made or authorized to be made by me.

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by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Graham MCCLOREY

Date (Optional): 26-03-13

Signature: *Graham McClorey*

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

Electronic Patent Application Fee Transmittal				
Application Number:		16112371		
Filing Date:		24-Aug-2018		
Title of Invention:		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
First Named Inventor/Applicant Name:		Stephen Donald WILTON		
Filer:		Neil P. Shull/Debbie Colonna		
Attorney Docket Number:		4140.01500B0		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1000	1000

33474

Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:					
Miscellaneous:					
Total in USD (\$)					1000

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EFS ID:	34766739
Application Number:	16112371
International Application Number:	
Confirmation Number:	5407
Title of Invention:	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Stephen Donald WILTON
Customer Number:	153767
Filer:	Neil P. Shull/Debbie Colonna
Filer Authorized By:	Neil P. Shull
Attorney Docket Number:	4140.01500B0
Receipt Date:	04-JAN-2019
Filing Date:	24-AUG-2018
Time Stamp:	16:07:58
Application Type:	Utility under 35 USC 111(a)

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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#: 33478

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WASHINGTON, DC 20005

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(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/112,371	08/24/2018	Stephen Donald WILTON	4140.01500B0	5407

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL Undiscounted	\$500 \$1000	\$0.00	\$0.00	\$500 \$1000	04/03/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1635	514-044000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Sterne, Kessler, Goldstein
2 & Fox P.L.L.C.
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

The University of Western Australia

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Crawley, Australia

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

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☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☒ Applicant changing to regular undiscounted fee status.

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NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Eric K. Steffe/Date January 4, 2019Typed or printed name Eric K. SteffeRegistration No. 36,688



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/112,371	03/12/2019	10227590	4140.01500B0	5407

153767 7590 02/20/2019
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
 1100 NEW YORK AVENUE, N.W.
 WASHINGTON, DC 20005

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

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APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Stephen Donald WILTON, Applecross, AUSTRALIA;
 The University of Western Australia, Crawley, AUSTRALIA;
 Sue Fletcher, Bayswater, AUSTRALIA;
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